Supreme Court, U.S.
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No. _____

In the Supreme Court of the United States

UNITED STATES OF AMERICA, EX REL.
JACK OBEYDEAN SWAFFORD, A/K/A DEAN J. SWAFFORD,
Petitioner,

v.

BORGESS MEDICAL CENTER,
A NONPROFIT MICHIGAN CORPORATION, ET AL.,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

1. Whether the District Court Judge erred in granting Respondents' Motions for Summary Judgment given numerous and pervasive genuine issues of material fact such as whether Respondents submitted false claims notwithstanding, for example:

    A. The HCFA Medicare Carrier's Manual;

    B. The HCFA Medicare Provider's Manual;

    C. Other Alternative, But Relevant, Regulations;

    D. The Requisite Physician Standard of Care; and

    E. Respondents' Admitted Practice.

2. Whether Respondents' actions of merely reviewing a technician's work product of reportedly negative venous ultrasound studies, with the Respondent physician merely assuming that portions of the venous ultrasound not addressed in the worksheet, or the technician's mere conclusion(s) contained therein, were negative without reviewing any hard data (prints/video) of the venous ultrasound study constitutes a "reading or interpretation" of the results of the study as required in the "Professional Component (26 Modifier); and, whether the technician's worksheet is a "result" of the venous

ultrasound study within the reasonable meaning of the "professional component"?

3. Whether Respondents had actual or constructive notice of the billing requirements of the HCFA Medicare Carrier's Manual given its publication in the Federal Register.

4. Whether Claimant relied upon, to his detriment, the trial court's direction with respect to the "first phase" of discovery by focusing upon what the "practice" was of the physicians, technicians and technologists with respect to reporting and "interpretation" of venous ultrasound studies reported as negative, and whether the District Court's ruling on the issue of Respondents' "intent" was proper in light of same.

PARTIES TO THE PROCEEDINGS

The parties to the proceedings are:

PETITIONER

Jack Obeydean Swafford, also known as Dean J. Swafford. Mr. Swafford is the *qui tam* Relator. Mr. Swafford is a vascular technologist who has been an employee, at different times, of Respondents Borgess Medical Center, Bronson Methodist Hospital and John T. Collins, Jr., M.D. and Randy Smejkal, M.D.,P.C.,

RESPONDENTS

The Respondents are health care practitioners, their professional corporations and other healthcare entities in Michigan. The commonality among the Respondents is the performance of venous ultrasound studies, designed to assist in the diagnosis of deep vein thromboses (blood clots in the legs), and the claims made to the federal government for services rendered to Medicare, Medicaid and CHAMPUS participants. The Respondents consist of the following individuals and entities:

Borgess Medical Center, a nonprofit Michigan corporation,
Advanced Vascular Surgery, P.C., a Michigan professional corporation,
Krishna Jain, M.D.,
John Munn, M.D.,
Eugene Simoni, M.D.,
John T. Collins, Jr., M.D. and Randy Smejkal, M.D., P.C., a Michigan corporation,
John T. Collins, Jr., M.D.,
Randy Smejkal, M.D.,

James Mclaren, M.D.,
Healthcare Midwest General & Surgeons, a/k/a Healthcare Midwest, P.C., a Michigan corporation,
Mark Tagett, M.D.,
Philip Borozan, M.D.,
Solomon K. Samuels, M.D., P.C., a Michigan corporation,
Solomon K. Samuels, M.D.,
Padraic Carmody, M.D.,
Vascular Specialists, P.C., a Michigan corporation,
Karim Abedel Abushmaies, M.D., and
M. Abidur Rahman, M.D.

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OPINIONS BELOW

The opinion and order of the United States District Court for the Western District of Michigan was reported at 98 F. Supp.2d 822 (W.D. MI 2000) and is reproduced in App. A. The opinion of the Court of Appeals was issued on December 12, 2001, and was not reported. It is reproduced in App. B.

JURISDICTION

The opinion of the United States Court of Appeals for the Sixth Circuit was issued on December 12, 2001. This Court has jurisdiction to entertain this Petition pursuant to 28 U.S.C. §1254(1).

STATUTORY PROVISION INVOLVED

The statutory provision involved in this case is False Claims Act, 31 U.S.C. §3729, which, in pertinent part, provides that:

> "(a) Liability for certain acts.--Any person who–
>
> > (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
> >
> > (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
> >
> > * * *

(7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person...

* * *

(b) Knowing and knowingly defined.--For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information--

(1) has actual knowledge of the information;

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

(c) Claim defined.--For purposes of this section, "claim" includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any

portion of the money or property which is requested or demanded.

STATEMENT OF THE CASE

A. INTRODUCTION

This action is a *qui tam action* brought pursuant to 31 U.S.C. §3729-3731, and arises from Respondents acts of submitting fraudulent claims to the federal government for health care services allegedly provided to participants in federal health care programs. The individual Defendants, all vascular surgeons, submitted claims to the federal government for "reading or interpretation" of venous Doppler ultrasound studies, a diagnostic study designed to assist in the diagnosis of the presence or absence of deep vein thromboses (blood clot in the legs or arms).

The mechanics of the study are performed by technicians or technologists. In those circumstances where the technician/technologist reported the studies as negative for a deep vein thrombosis the "analysis" of the vascular surgeon was limited to reviewing the subject worksheet compiled by the technician/technologist. Notwithstanding that the vascular surgeon looked at no objective study data, the vascular surgeon submitted a claim to the federal government for the "reading or interpretation" of the venous ultrasound study conducted. The vascular surgeon simply reworded and/or plagiarized from the "worksheet" of the technician/technologist as a premise for the payment claim submitted. Examples of a technician's completed worksheet, and a physician's report are provided in App. E.

B. PROCEEDINGS BELOW

Petitioner filed suit in United States District Court, Western District of Michigan, asserting a claim under the False Claims Act ("FCA"), 31 U.S.C. §3729, et seq. The "*qui tam*" provision of the FCA permits a private citizen to bring actions under the FCA on behalf of the federal government in circumstances where the government opts not to undertake the litigation.

On February 18, 2000, the Honorable David W. McKeague granted Respondents' Motions for Summary Judgment pursuant to Fed. R. Civ. P. 56(c) on the grounds that there was no genuine issue as to any material fact and that the Respondents were entitled to a judgment as a matter of law.

Thereafter, an appeal was pursued to the Sixth Circuit Court of Appeals. On December 18, 2001, the Court of Appeals issued a per curium opinion affirming the trial court.

C. REASONS FOR GRANTING THE WRIT

1. THE QUESTION PRESENTED IS IMPORTANT

Review of this matter by this Honorable Court is necessary to review and address the propriety of: (1)the finding by the trial court that claims submitted by the Respondents were not false claims because (a) the federal government had never issued any regulations to follow; and (b) that the relevant Standard of Practice was immaterial to the analysis - notwithstanding the absence of applicable opinions from this Honorable Court and based upon a misinterpretation by the lower court of case authority (regarding the intent element of a False Claims Act claim); and, (2) the trial court limiting discovery and then granting

Summary Judgment based on findings in areas where no discovery was permitted.

It has been long the policy of this Honorable Court that dismissal of a matter by summary judgment is not the favored treatment of matters involving important public issues. The authors in Wright, Miller and Kane, Federal Practice and Procedure: Civil 3d, §2732, p. 99, wrote:

> "Despite this principle of uniform treatment, a review of summary judgment decisions rendered in complex cases and cases involving important public issues suggests that Rule 56 motions may be much less successful in this form of litigation than in other, simpler matters. The notion that summary judgment may not be appropriate in complicated and important litigation seems to have its roots in a series of Supreme Court decisions in the 1940s, culminating with the Court's opinion in Kennedy v. Silas Mason Company. That case was an action by employees for overtime pay under the Fail Labor Standards Act. In his opinion for the Court, Justice Jackson recognized that the case posed an 'extremely important question, probably affecting all cost-plus-fixed-fee war contractors * * *.' As a result of the potential consequences of a decision on the overtime question, the Court reversed the district court's grant if a Rule 56 motion."

The issued posed in this matter, one of health care fraud, is by all means an important public issue.

In *The Department of Health and Human Services And The Department of Justice Health Care Fraud and Abuse Control Program Annual Report For FY 1998*, published at http://www.usdoj.gov/ag/98hipaa_ar.htm#a, for 1998 the government reported:

> "The detection and eradication of health care fraud and abuse is a top priority of federal law enforcement....
>
> The second year of operation under the Health Care Fraud and Abuse Control Program saw continuing returns to the Medicare Trust Fund, a rise in the number of individuals excluded from participation in federally-funded health care programs, and the initiation and enhancement of important efforts to *prevent* health care fraud and to safeguard the quality of care furnished to beneficiaries under those programs.
>
> *Civil and Criminal Enforcement Actions*
>
> Federal prosecutors filed 322 criminal cases in health care fraud cases in 1998 -- a 14 percent increase over the previous year, and 326 defendants were convicted of health care fraud-related crimes. Also in 1998, 107 civil cases were filed, and at the end of the year 3,471 civil matters were pending.
>
> *Monetary Results*
>
> In 1998, the Federal Government won or negotiated more than $480 million in judgments, settlements, and administrative impositions in health care fraud cases and

> proceedings. As a result of these activities, as well as prior-year judgments, settlements, and administrative impositions, the Federal Government in 1998 collected $296 million. It should be noted that some of the judgments, settlements, and administrative impositions in 1998 will result in collections in future years, just as some of the collections in 1998 are attributable to actions from prior years.
>
> More than 92 percent ($271 million) of the funds collected and disbursed in 1998 were returned to the Medicare Trust Fund. An additional $9 million was recovered as the federal share of Medicaid restitution." (Emphasis added)

The allegations in this action are of fraudulent claims having been submitted to the federal government for services never rendered. The context of the fraudulent claim that underlies this action merits scrutiny by this Honorable Court. In conflict are the claims by the Petitioner that the "services" billed for by the Respondents fail to meet the definition of a compensable "physician's service" under traditional concepts of medical care; and, the retort by the Respondents that the federal government has not specifically legislated on the health care service at issue therefore Respondent's interpretation of the factual services that are encompassed within the billing code is reasonable. **SCRUTINY AND REVIEW BY THIS HONORABLE COURT IS NECESSARY INASMUCH AS THERE IS NO RELEVANT PRECEDENT FOR INTERPRETING HEALTH CARE BILLING CODES, WHERE NO DEFINITION HAS BEEN PROVIDED BY THE FEDERAL GOVERNMENT.** Without the review requested

health care providers, with impunity, will continue to bill for services that do not meet the definition of such a service as recognized by the health care community.

Review by this Honorable Court is further warranted by reason of the trial court's limitation on available discovery. The discovery order, App. D, substantively limited the Plaintiff's discovery. Notwithstanding such a limitation, in part the District Court's summary judgment addressed areas that discovery was not permitted in. Because discovery was limited Petitioner was unable to fully developed factual proof to support his claim, thereby placing him in the untenable position of defending against a summary judgment motion in an area not-yet made part of the case.

In Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986) on the issue of the propriety of a summary judgment this Honorable Court wrote:

> "As to materiality, the substantive law will identify which facts are material. Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment...(Citation omitted). This materiality inquiry is independent of and separate from the question of the incorporation of the evidentiary standard into the summary judgment determination. That is, while the materiality determination rests on the substantive law, it is the substantive law's identification of which facts are critical and which facts are irrelevant that governs. Any proof or evidentiary requirements imposed by the substantive law are not germane to this inquiry, since

> materiality is only a criterion for categorizing factual disputes in their relation to the legal elements of the claim and not a criterion for evaluating the evidentiary underpinnings of those disputes." (Emphasis added)

The substantive law at issue, the False Claims Act, addresses the scienter element, and the necessary state of mind that must be found before liability could be premised. The trial court in it's summary judgment determination erred in it's interpretation of the FCA, and, accordingly, erred in its decision on the summary judgment motion.

(a) PETITIONER WAS NOT PERMITTED TO CONDUCT DISCOVERY ON ISSUES THAT WERE DECIDED BY THE TRIAL COURT ON SUMMARY JUDGMENT

Petitioner initiated the instant lawsuit alleging that Respondents fraudulently submitted claims to the federal government for healthcare services that were not rendered. The Respondent physicians submitted claims for the "reading or interpretation" of venous doppler ultrasound studies but did not review any objective test data (e.g. videotapes of the studies). Rather, when a study was reported as negative the Respondent physicians simply reworded and/or plagiarized the vascular technician's "worksheet" into a form of a "physician's ultrasound report" and submitted a claim for the service allegedly rendered. Respondents filed their respective Answers, denying the assertion. Thereafter, Respondents filed Motions for Summary Judgment and/or Motion to Dismiss.

In support of one such motion was the affidavit of Respondent Dr. Krishna Jain. **In his affidavit, Dr. Jain conceded the fact of the "physician interpreting" practice as alleged by Petitioner.** App. C at pages C-2 and C-3.

Similarly, Respondent Dr. Borozan filed an affidavit in support of the Motion for Summary Judgment. **Dr. Borozan expressly conceded the "physician interpretation" practice as alleged by Petitioner.** App. C, at pages C-6 and C-7 . Thereafter, a second Affidavit of Dr. Borozan was filed, indicating that in rendering an "interpretation" of the venous ultrasound study the "interpreting" vascular surgeon also took into account "communications" with the technician. App. C., at pages C-9 through C-16.

In light of Respondents' *factual* claim the trial court ordered an "initial" phase of discovery, one designed to investigate, only, the "interpretation" practices of the Respondent physicians. See the discovery order reproduced in App. D. Petitioner's counsel embarked upon an "initial" phase of discovery as ordered by the court and limited his discovery requests to the physicians' alleged "interpretation" practices, only.

Following the "initial" phase of discovery, on September 29, 1999 and October 13, 1999, Respondents re-filed their motions for summary judgment. The District Court held a hearing on the motions on November 29, 1999. On February 18, 2000, the District Court entered an order and opinion granting summary judgment in Respondents' favor.

The first phase of discovery, as outlined by the District Court, was to be limited to what the mechanistic "interpretation practice" was of the Respondent physicians, hospital-based technicians and technologists with respect to the "interpretation of and reporting of" venous ultrasound studies. *The District Court limited the scope of discovery and, as an example, limited the number of depositions which could be taken by Plaintiff in this regard.* However, the District Court's decision to dismiss Plaintiff's complaint, as reflected in its opinion dated February 18, 2000 (App. A.),

was also predicated upon issues relating to the respondent physicians' scienter - and area that was outside of the discovery permitted. Petitioner relied, to his detriment, upon the District Court's direction and limitation with respect to the first phase of discovery by focusing upon what the "practice" was of the Respondent physicians, hospital-based technicians and technologists with respect to "interpreting and reporting" of venous ultrasound studies, particularly those reported as negative.

In U.S. v. Oakwood Downriver Medical Center, 687 F.Supp 302, 309 (E.D. Mich 1988), a False Claims Act action involving assertions of Medicare fraud, the trial court recognized the following with respect to the Defendants Motion for Summary Judgment:

> "Defendants Winter and Zack Fields request this Court grant their motion for summary judgment under F.R.Civ.P. 56. Defendant Winter, by filing his affidavit, asserts that he did not knowingly, recklessly, or with deliberate ignorance prepare or submit false claims on behalf of Oakwood. The Plaintiff's responses to this motion are appropriate. First, this motion was filed almost nine (9) months prior to discovery cut-off and thus matters which may dispute the affidavit may yet be discovered. Second, the attachments to Plaintiff's brief in response to Defendants' motion for summary judgment clearly raise a fact question regarding whether Defendant Winter knew the substance of the false forms. Finally, as stated previously, the Defendants' actual and stated intent may not absolutely excuse them from liability under the False

> Claims Act; i.e. the Plaintiff need not prove actual intent to submit false claims.
>
> Therefore, based on the above, Defendant Winters and Zack Fields motion for summary judgment is DENIED." (Emphasis added)

See also, U.S. v. Bliss, 667 F.Supp. 1298, 1311 (E.D.Mo. 1987) (Summary judgment may not be granted if the non-moving party has had inadequate time to conduct discovery); Celotex Corp. v. Catrett, 477 U.S. 317, ----, 106 S.Ct. 2548, 2552-53, 91 L.Ed.2d 265 (1986) (summary judgment may be granted after adequate time for discovery). This rule prevents the possibility that no genuine issue has been presented merely because the non-moving party has had an inadequate opportunity to investigate the facts.

A grant of summary judgment in the context of this matter was error on the part of the District Court must be reviewed and/or reversed by this Honorable Court.

(b) THE DISTRICT COURT ERRONEOUSLY HELD THAT THE FALSITY OF A CLAIM CANNOT BE ESTABLISHED BY REFERENCE TO THE APPLICABLE RULES AND REGULATIONS AND/OR THE PREVAILING AND APPLICABLE STANDARD OF PRACTICE

In granting summary judgement for the Respondents the District Court held that Petitioner failed to demonstrate that the claims submitted were false claims on the reasoning that (a) the federal government had not published rules and/or regulations relative to the Respondents; and, (b) that reference to the attending Standard of Practice was irrelevant. The

decision of the District Court must be reviewed as both conclusions were erroneous.

An individual who qualifies for the federally funded Medicare program, is "entitled to have payment made to him or on his behalf . . . for medical and other health services...". 42 U.S.C. §1395(k)(a)(1). The term "medical and other health services", is defined at 42 U.S.C. §1395(x)(s), and includes "physician services". In turn, the term "physician services" is defined at 42 U.S.C. §1395(x)(q), as:

> "[t]he term 'physician services' means **professional services performed by physicians**, including surgery, consultation, and home, office and institutional calls...". (Emphasis added)

The key issue submitted to the to the District Court was whether the activities of the Respondents in plagiarizing the worksheets of the technicians and/or technologists, were, in fact, rendering "physician services" and/or "professional services" as contemplated by federal law.

The federal Medicare and Medicaid programs are administered by the Health Care Financing Administration ("HCFA"). HCFA has been empowered to issue rules and regulations concerning the administration of the Medicare and Medicaid programs. One such rule issued is HCFA's criteria for a physician to be paid for providing "services" to a Medicare/Medicaid program participant, which provides:

> "(1) The services are **personally furnished** for an individual beneficiary by a physician.
>
> (2) The services **contribute directly** to the diagnosis or treatment of an individual

beneficiary.

(3) The services ordinarily require performance by a physician.

(4) In the case of radiology or laboratory services, the additional requirements in §415.120 or §415.130, respectively are met."

42 U.S.C. §415.102. For a physician to be paid for radiology services *(inclusive of the venous ultrasound studies at issue in this matter)* HCFA requires the *"identifiable", "direct",* and *"discrete" diagnostic* service, and an *"interpretation"* furnished to an individual.

While Defendants insist that there are no regulations relating to their billing of the federal government for venous ultrasounds, they offer only their opinion as to "reasonable" conduct in the circumstance. On the other hand, Plaintiffs have offered relevant evidence, including expert affidavit testimony asserting:

- The rules/regulations/bulletins, promulgated by HCFA, including, but not limited to, 42 USC §§ 415.102, 415.120, 415.130, and 1395, are applicable to a physician providing a "service" or billing with respect thereto, including "professional component" billing for venous doppler ultrasounds from 1991 to date.

- The HCFA Medicare Carrier Manual interprets and explains the HCFA rules and regulations and directly relates and applies to physician/hospital, etc. with respect to "professional component" and/or "technical component" billing for venous doppler

ultrasounds at issue in this lawsuit.

- HCFA Medicare Carriers Manual §2020 is applicable to Defendants' "reading"/"interpretation" of venous Doppler studies and billing and payment therefore.

- Defendants must personally furnish a "service" to a "beneficiary" which contributes directly to the diagnosis or treatment of the beneficiary, in order to properly bill and/or receive payment for the "service" in question with respect to any Medicare/Medicaid or CHAMPUS patient (Civilian Health & Medical Program of United States).

- "Physician services" must include the physician's personal examination of the patient, or visualization (video or photographs at a minimum) of some aspect of the patient's condition in question, without the "interposition of a third person's judgment" including that of a technician or technologist.

- Physicians ("service providers") are informed or knowledgeable of Medicare/Medicaid rules, regulations and interpretation/application thereof through various sources including Medicare reports, Medicare Bulletins, billing/documentation requirements of the fiscal intermediary, Providers Manual Medicare Part B Bulletins, published or disseminated and guidelines of the fiscal intermediary.

See the affidavit of Robert Schwartz, M.D., attached in App. F.

Respondents in denying any fraudulent billing practice predicate their position upon their "interpretation" of the "26 Modifier" code, a coding scheme that creates a distinction between the *professional component* and *technical component* of a given service. It is the position of the Respondents that they may bill for the "professional component" of the test by their review of the technician's worksheet, only. However, such a result necessitates a leap in logic that the review of a subjectively-prepared technician worksheet is the same as a review of the underlying object ultrasound films.

The term "Professional component" is defined in the CPT Coding Manual for diagnostic studies and procedures, published by the American Medical Association, as involving a physician's *reading and interpretation of all test results*. The term "technical component", is defined in the CPT manual as the actual performance of the test, and does not require the skill of a physician. To accept the position of the Respondents is to accept the assertion that the reviewing of a technician's worksheet, and plagiarizing the results, is the "reading and interpretation of all test results".

The Medicare Carriers Manual, §2020, ("Manual") is published by HCFA and provided to carriers to interpret and explain HCFA regulations. **THE MANUAL EXPRESSLY INDICATES THAT "PHYSICIANS SERVICES" ARE NOT TO BE INCLUSIVE OF A THIRD PERSON'S JUDGMENT**.

> "Physicians' services include diagnosis, therapy, surgery, and consultation. The services must be rendered by the physician. The service may be considered to be a physician's service where the physician either examines the patient in person or is able to visualize some aspect of the patient's condition

> without the interposition of a third person's judgment. Direct visualization would be possible by means of X-rays, electrocardiogram, and electroencephalogram tapes, tissue samples, etc. Thus, for example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram reading that has been transmitted via telephone (i.e., electronically rather than by means of a verbal description) is a covered service." (Emphasis added)

Physicians are entitled to Medicare payment only if the professional "services" were performed by physicians. 42 U.S.C. §1395(x)(q), i.e. pursuant to HCFA regulations, the "service must be personally furnished to a beneficiary by a physician".

Respondents had notice of these rules as both the HCFA Carrier's Manual, as well as the HCFA Provider's Manual, are published in the Federal Register. It is well established that publication in the Federal Register is legally sufficient notice to all interested or affected persons regardless of actual knowledge or hardship resulting from ignorance. *Jones v. United States*, 121 F.3d 1327 (C.A. 9 1997) cert. den. 118 S.Ct. 1802, 140 L.Ed.2d 942; *San Pablo v. I.N.S.*, 4 F.Supp.2d 881 (D. Ariz. 1997); *Camp v. United States Bureau of Land Management*, 17 F.Supp.2d 1167 (D. Or. 1998).

In *Jones*, supra, the plaintiffs were former holders of an unpatented mining claim on federally-owned land. By legislation enacted on October 5, 1992, every holder of an unpatented mining claim on federal land was required to pay a per-claim annual fee to the Secretary of the Interior by August 31, 1993. The statute provided that failure to pay the

required fee would conclusively constitute an abandonment of the unpatented mining claim by the claimant. Prior to the enactment of the 1992 Act, the plaintiffs were not required to make any payments to the government. The 1992 Act was published in the Federal Register.

The plaintiffs did not pay the fee required by the 1992 Act and their mining claims were voided by the Bureau of Land Management ("BLM"). The Interior Board of Land Appeals affirmed the BLM's decision. Plaintiffs challenged the decision in the district court on constitutional grounds. The district court granted summary judgment in favor of the government.

The plaintiffs, in *Jones*, supra, contended that they did not receive actual or individual notice of the new requirements whereas the government sent individual notices to all other holders of mining claims in California. The plaintiffs contended that their due process and equal protection constitutional rights were violated. Affirming the district court's decision, the Ninth Circuit Court of Appeals held:

> "Jones is also charged with knowledge of the 1992 Act's requirements by virtue of the notice published in the Federal Register on November 16, 1992. This notice contained a clear statement describing the new requirements imposed by the 1992 Act. 'Publication in the Federal Register is legally sufficient notice to all interested or affected persons regardless of actual knowledge or hardship resulting from ignorance'" (citations omitted)

Jones, supra at 1330; Cf. *Friends of Sierra R.R., Inc. v. I.C.C.*, 881 F.2d 663, 667-668 (C.A. 9 1989).

Despite notice provided in the form of published regulations, Respondent physicians have not independently (objectively) interpreted the venous ultrasound studies at issue without the "interposition of a third person's judgment."

There is a clear distinction between a technologist and an interpreting physician. The technician/technologist's proper technical performance of the venous ultrasound is important as to the technical accuracy of the study, i.e., in the event the study is not properly performed, the study may be reported as negative for deep vein thrombosis when in fact a blood clot may be present. However, the physician interpretation is necessary for the integration of the findings concerning a given patient and the plan of care for that patient, as well as an important check as to the accuracy of the study. Finally, there can be disagreement as to whether the study is or may be negative for a blood clot. Such was conceded by various technicians/technologist and physicians.

When interpreting a statute and related regulations, the court looks to the **common** meaning of the terminology used. If Congress has not directly addressed the issue, or if the statute **is clearly ambiguous**, the court is required to give the agencies interpretation of the statute great deference, otherwise the court may exercise its judgment if the regulation is not actually stated.

The absurdity of Respondents' position is further illustrated in Respondent', Healthcare Midwest, P.C., Mark Tagett, M.D., and Philip Borozan, M.D., claim in their Brief in Support of Motion for Summary Judgment, that the physician's ability to "form a mental image of the patient's condition from the objective data provided by the technician/technologist after he or she performs the 'technical component' of the study" constitutes a billable physician service under Medicare Carriers Manual §2020A. *In other*

words, according to Defendants' argument, the physician's IMAGINATION of what the patient's veins MUST HAVE looked like on the ultrasound is a "physician service" justifiably billable to the federal government.

When interpreting HCFA regulations, "standard definitions, accounting, statistics and reporting practices which are widely accepted in the hospital and related fields are followed." *Cf.* 42 C.F.R. §413.20(a). The Section further provides that physicians may be paid for "radiology" services only when they are "identifiable, direct, and discrete diagnostic or therapeutic services furnished to an individual beneficiary, such as interpretation of x-ray plates, angiograms, myelograms, pyelograms, or ultrasound procedures." The common definitions of the operative terms are as follows:

> "Identifiable" is defined as: "to recognize as being or show to be the very person or thing known, described, or claimed"

Webster's New World Dictionary, 3rd College Addition, Simon and Schuster, Inc., Pg. 669 (1988).

> "Direct", is defined as "with nothing or no one between; immediate, close, firsthand, or personal [direct contact, direct knowledge].

Id., at page 389.

> "Discrete" is defined as: "separate and distinct: NOT ATTACHED TO OTHERS; unrelated. (2) made up of distinct parts; discontinuous".

Id., at page 392.

> "Diagnosis", is defined as: "the act or process of deciding the nature of a diseased condition by examination of the symptoms (2) a careful examination and analysis of the facts in an attempt to understand or explain something [a diagnosis of the economy] (3) a decision or opinion based on such examination"

Id., at page 379.

> "Interpret" is defined as: "to have or show ones own understanding of the meaning of; construe, or to bring out the meaning of;

Id., at page 706.

None of the services purportedly rendered met either the spirit, or the letter, of the applicable regulations. It was error on the part of the District Court to determine that no federal regulations existed that governed the conduct of the Respondents. On several levels the federal government has determined that the actions of the Respondents was inappropriate.

Similarly, the district court erred with respect to it's determination concerning the inapplicability of the attending Standard of Practice. Contrary to the conclusion of the district court reference to the attending Standard of Practice can be utilized to determine the falsity of a claim.

In U.S. v. NHC Healthcare Corp., 115 F.Supp.2d 1149, 1152 (W.D. MO, 2000) the trial court had before it a False Claims Act action asserting that the defendant billed for healthcare services in the nursing home that were never rendered. In addressing the proof necessary to establish a false claim the trial court wrote:

"Therefore, the Court is left with the issue of whether any factual scenario reasonably supported by the allegations in the Complaint can support the claim that the Defendant submitted a false or fraudulent claim. Proving that one of the claims set forth in the Complaint is false or fraudulent is a difficult proposition because these claims were necessarily based on somewhat subject regulations, rules and laws pertaining to proper health care maintenance. Certainly if the Defendant billed the United States for specific services that it never rendered then that claim would be fraudulent and properly actionable under the FCA. To the extent that the Government alleges this theory it is clearly a cognizable theory. At the other end of the spectrum the Court would not find a cognizable claim under the FCA if the United States simply disagreed with a reasonable medical or care treatment administered by the Defendant. In that case, the Defendant would obviously be innocent of fraud in its billing practices, but rather it would simply be at odds with the entity that pays the treatment it provided. (Citation omitted) Unfortunately this case, as with almost all difficult legal judgments, falls somewhere between these clear examples.

The main thrust of the argument from the Government is not that the Defendant completely failed to treat the two residents in question. Rather, the Government argues that NHC was so severely understaffed that it could

not possibly have administered all of the care it was obligated to perform under the Medicare and Medicaid programs. If the Defendant billed Medicare and Medicaid for each individual act of care (i.e. turning, cleaning, administering drugs, food care, etc.) then this case would be relatively straightforward; the Court could simply compare what items NHC billed the United States for and what acts were actually performed. Unfortunately again, this is not the billing procedure.... Therefore, the Court holds that in order for the Plaintiff to prove that it was fraudulently billed for the care given to the two residents at issue in this lawsuit it must demonstrate that the patients were not provided the quality of care which promotes the maintenance and the enhancement of the quality of life.

Obviously, this is an amorphous standard in need of further clarification. However, at this stage in the litigation the Plaintiff need not support the allegations in the record, it need only plead a sufficient cause of action." (Emphasis added)

Reference to the "quality of care" in the NHC, supra, matter is a reference to the attending Standard of Care. Just as the government in NHC, supra, reasoned that appropriate care could not come from an understaffed facility, and hence a false claim had to have been filed, is no different from the allegations in this matter. In this matter the claims submitted by the Respondents were false claims because the Respondents could not have rendered a diagnosis, or have provided a compensable medical service, from a review of a technician's

worksheet, only. To that end, a demonstration by the Petitioner of the applicable Standard of Practice was appropriate.

(c) THE DISTRICT COURT ERRED THAT THERE WAS NO GENUINE ISSUE OF MATERIAL FACT WHETHER RESPONDENTS HAD THE NECESSARY SCIENTER TO HAVE SUBMITTED FALSE CLAIMS

The False Claims Act (31 U.S.C. §3729-3731) (hereafter the "FCA") was enacted in 1873 to protect the federal Treasury from fraud. *Pogue v. American Health Corp., Inc.*, 941 F. Supp. 1507, 1512 (M.D. Tenn. 1996), citing S. Rep. No. 345, 99th Cong., 2d Sess. 4 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5396. The FCA was amended in 1986 "to enhance the government's ability to recover losses sustained as a result of fraud against the government", and lessened the scienter of a false claim to include actual knowledge, deliberate ignorance, OR reckless disregard for the truth. *Id.* at 1512.

Petitioner in this case has alleged that Respondents have violated several provisions of the FCA, such as 31 U.S.C. §3729(a)(1) (knowingly presenting a false or fraudulent claim for payment or approval); 31 U.S.C. §3729(a)(2) (knowingly causing to be made or used a false record or statement to get a false or fraudulent claim paid by the government) and, 31 U.S.C. §3729(a)(3) (conspiring to defraud the government by getting a false or fraudulent claim allowed or paid). The statute addresses the scienter element of the claim and recognizes:

> "(b) Knowing and knowingly defined. For purposes of this section, the terms 'knowing' and 'knowingly' mean that a person, with respect to information–
>
> has actual knowledge of the information;
>
> (2) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (3) acts in reckless disregard of the truth or falsity of the information,
>
> **and no proof of a specific intent to defraud is required**." (Emphasis added)

31 U.S.C. § 3729(b). Notwithstanding the clear and unambiguous language in the FCA, concerning the "intent" of the person submitting the false claim, the trial court required a more onerous showing than required by the statute. Specifically, the district court in it's opinion wrote:

> "Hence, to prevail under § 3729(a), a plaintiff must establish at least three elements: first, that the defendant knowingly presented or caused to be presented a claim to the United States for payment or approval; second, that the claim was false or fraudulent; and third, **that the defendant knew the claim was false or fraudulent**." (Emphasis added)

App. A, at page 8. Whereas the statute does not require a specific intent to defraud the trial court did. IT WAS ERROR FOR THE TRIAL COURT TO HOLD THAT THE STANDARD WAS THAT THE "DEFENDANT KNEW THAT THE CLAIM WAS FALSE."

In U.S. v. Mackby, 243 F.3d 1159, 1165 (9th Cir. 2001), a panel of the Court of Appeals held:

> "Under the FCA, 'knowing' and 'knowingly' mean that a person, with respect to information--(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b); (Citation omitted) The requisite intent is the knowing presentation of what is known to be false. (Citation omitted) 'Known to be false' does not mean scientifically untrue, but 'a lie.' (Citation omitted).
>
> 'Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law....' (Citation omitted) PARTICIPANTS IN THE MEDICARE PROGRAM HAVE A DUTY TO FAMILIARIZE THEMSELVES WITH THE LEGAL REQUIREMENTS FOR PAYMENT. *Id.* at 64, 104 S.Ct. 2218." (Emphasis added)

In U.S. v. Cabrera-Diaz, 106 F.Supp.2d 234, 239 (D. Puerto Rico, 2000), the trial court held:

> The case law construing 31 U.S.C. §§ 3729(b) affirms the clear language of the statute and the intentions of Congress that "no proof of specific intent to defraud is required". (Citations omitted)

The district court in this matter applied the wrong standard in determining that summary judgement on behalf the Respondents was appropriate. Of all the Respondents in this matter only one, Jain Krishna, M.D., asserts that any effort was made to contact the federal governments and determine the propriety of the claims being submitted, despite a DUTY to do so. Clearly, had the district court considered the appropriate standards a different result would have followed the Motion for Summary Judgement.

(d) THE COURT OF APPEALS ERRONEOUSLY SUSTAINED THE ORDER OF THE TRIAL COURT

The decision of the Court of Appeals is similarly erroneous. In an unpublished, per curium, opinion, see App. B., the Court of Appeals cited to two cases, *Hagood v Sonoma County Water Agency,* 81 F.3d 1465 (9th Cir. 1996) and *Hindo v University of Health Sciences*, 65 F.3d 608 (7th Cir. 1995), neither of which are applicable, in sustaining the dismissal of the trial court.

In it's opinion the Court of Appeals wrote:

> "1) Services falling below a requisite standard of care, without more, is insufficient to state a claim for government reimbursement of venous ultrasound testing services. *See, e.g., Hagood v. Sonoma County Water Agency,* 81 F.3d 1465, 1478 (9th Cir.1996)."

Hagood, supra, is distinguishable as the matter did not deal with issues of "standard of care". Rather, *Hagood, supra*, involved a public works project (the building of a dam) and the determination and allocation of responsibility for the costs of construction. Contrary to the application provided by

the Court of Appeals, the issue in Hagood, supra, was whether the defendant therein, the Sonoma County Water Agency, acted with a "blind eye" or "reckless indifference" when it placidly relied on a cost allocation made by the project manager, the Army Corps of Engineers. The asserted "false claim" in *Hagood, supra*, was that the Defendant improvidently benefitted by the objectively flawed analysis of the Army Corps of Engineers.

Clearly *Hagood*, supra, does not involve a question of the applicable standard of care. In the present situation the applicable standard of care is an issue as the "physician services" rendered by the Respondents failed to amount to "physician services" as they failed to comply with the applicable standard of care. The natural result was the submission of a payment claim to the federal government to an act that does not amount to a "physician service" as measured by objective standards.

The Court of Appeals also referenced *Hindo*, supra, and stated:

> "2) The venous ultrasound reports were not knowingly fraudulent. *See, e.g., Hindo v. University of Health Sciences,* 65 F.3d 608, 613 (7th Cir.1995)."

In *Hindo, supra*, the defendant, University of Health Sciences / The Chicago Medical School, contracted with a local Veterans Administration Medical Center ("VAMC") to provide radiology resident physicians to render services to patients. The VAMC had the obligation to obtain the necessary funding to pay for the services of the radiology resident physicians.

For the claims at issue there was no dispute that the radiology resident physicians provided the health care services contracted. The problem in *Hindo, supra*, rather was that the VAMC never successfully obtained funding for the services that it accepted.

Hindo, supra, is distinguished from this instant action in that there was no issue in *Hindo, supra*, concerning the nature of the services rendered. Radiology services were contracted; and, as the issue is not raised, the only logical conclusion to draw is that radiology services were provided. In the instant action the assertion is made that "physician services" were provided by the Respondents when the mimic, or aped, or plagiarized the worksheets prepared by the technicians. This instant action is markedly distinguished from the *Hindo, supra*, action.

CONCLUSION

The issue presented to this Honorable Court is an important issue. Health care fraud is an onerous problem and efforts are constantly underway to eliminate the problem. The Respondents in this action clearly failed to render any meaningful service to federal health care program participants. The claims submitted to the federal government for those services were patently false claims as no "physician service" as suggested by the claim, was ever provided,

The grant of summary judgment by the trial court, and the affirmation by the Court of Appeals, was inappropriate. The trial court purposefully limited the scope of discovery in this matter, yet rendered a decision on the dispositive motions based on conclusions that were outside of the scope of permitted discovery.

The claim made by Petitioner, Jack Obeydean Swafford, has merit which should be heard by a trier of fact. Petitioner prays this Honorable Court grant this Petition for Writ of Certiorari and undertake the appeal in this matter.

Respectfully submitted,

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APPENDIX A

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

No. 4:97-cv-116
[Filed February 18, 2000]

United States of America, Ex Rel. Jack Obeydean Swafford, a/k/a Dean J. Swafford,

Plaintiffs,

v.

Borgess Medical Center, a nonprofit Michigan Corporation, Bronson Methodist Hospital, a nonprofit Corporation, Advanced Vascular Surgery, P.C., a Michigan professional corporation, Krishna Jain, M.D., John Munn, M.D., Eugene Simoni, M.D., John T. Collins, Jr., M.D., and Randy Smejkal, M.D., James Mclaren, M.D., Healthcare Midwest General & Vascular Surgeons, a/k/a Healthcare Midwest, P.C., a Michigan Corporation, Mark Tagett, M.D., Philip Borozan, M.D., Solomon K. Samuels, M.D., P.C., a Michigan corporation, Solomon K. Samuels, M.D., Padraic Carmody, M.D., Karim Abedel Abushmaies, M.D.,and M. Abidur Rahman, M.D., Jointly and Severally,

Defendants.

JUDGES:
DAVID W. McKEAGUE,
UNITED STATES DISTRICT JUDGE.

OPINIONBY:
DAVID W. McKEAGUE

OPINION GRANTING DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

Now before the Court are defendants' motions for summary judgment, filed September 29 and October 13, 1999.[1] The Court held a hearing on the motion on November 29, 1999, and at that time took the matter under advisement. After having carefully considered the parties' arguments, both as made in their briefs and at the hearing, the Court will grant defendants' motions for summary judgment under Fed. R. Civ. P. 56(c) for the reasons set forth below.

I

Plaintiff is a registered vascular technologist employed by defendant John T. Collins, Jr., M.D., Randy Smejkal, M.D., and James McLaren, M.D., P.C., since December

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[1] The physicians' motion for summary judgment was filed September 29, 1999. Defendants Healthcare Midwest, P.C., Mark Tagett, M.D., and Philip Borozan, M.D. filed a separate motion for summary judgment on September 29, 1999. Defendant Borgess Medical Center filed its motion for summary judgment on October 13, 1999. Because defendant hospitals' and defendant physicians' arguments raise substantially identical legal issues, and because defendant hospitals' liability is contingent upon a finding of liability against defendant physicians, the Court will treat the separate motions collectively.

1997 and at the time of the filing of the parties' original summary judgment motions in October 1998. From 1992 until 1997, plaintiff was lead technologist at defendant Borgess Medical Center's vascular ultrasound department, and was also employed as a vascular technician at Bronson Methodist Hospital from 1988 to 1989. Accordingly, plaintiff participated in delivery of venous ultrasound studies ordered by defendant physicians and observed defendants' practices regarding the submission of Medicare/Medicaid reimbursement forms for ultrasounds performed on defendant physicians' patients.

For patients suspected suffered from risk factors for deep vein thrombosis ("DVT" or "blood clot"), defendant physicians would order a venous ultrasound study either at defendant hospital or at the offices of defendant clinics. Using ultrasound, the patient's venous system would be examined to determine the presence or absence of certain "normal" characteristics for five DVT risk factors.[2] The ultrasound study would typically be performed by either a technician or a technologist, who would then indicate the presence or absence of the five factors on a worksheet, which was then given to the physician for review. Because the technologist would summarize data for the physician, strict protocols were developed by defendant hospitals' vascular panels to ensure

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[2] The five factors are (1) "phasisity" (flow velocity changes in response to quiet respiration); (2) "augmentation" (an abrupt increase in venous flow result from manual compression of the extremity distal to the site of examination); (3) "spontaneity" (the presence of normal flow); (4) "compression" (the ability to fully compress the vein with a small amount of extrinsic pressure); and (5) "competence" (the abrupt cessation of blood flow in large and medium-sized veins) (Pl. Br. at 4).

accuracy and reliability. The technician/technologist was assigned to determine either the presence or absence of the characteristics, and to indicate either "positive" or "negative" for each factor.

Having performed the test itself, the technician/technologist was not required to grade the results or evaluate the results in comparison to a normative scale, tasks reserved to the physician in each instance. Defendant physicians would review the technician/technologists' worksheet, and then prepare a final report setting forth their findings and conclusions. Finally, defendant physicians signed the following statement prior to submitting the results for reimbursement: "I certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction."

The federal government's Health Care Financing Administration ("HCFA") administers the Medicare program in part through private contractors.[3] These contractors, or "carriers," serve as fiscal intermediaries for claims submitted by physicians or hospitals for reimbursement from Medicare. For their patients who are covered by Medicare, physicians may submit bills to the carrier for reimbursement of the

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[3] The Medicare program is administered by the Health Care Finance Administration, part of the Department of Health and Human Services. The program is authorized by Title VIII of the Social Security Act, and is divided into two parts. Part A of the Medicare program deals primarily with the reimbursement of hospitals for costs that they incur treating patients covered by Medicare, while Part B generally deals with the reimbursement of providers for physicians' services.

professional component of venous ultrasound studies. HCFA publishes a Carriers Manual, which provides carriers with guidelines for reimbursement of claims. To aid providers, including physicians, HCFA provides interpretive guidelines for submitting claims that are summarized in a Provider Handbook. HCFA also publishes all the above guidelines in the Federal Register.

A doctor who provides services to a Medicare or Medicaid recipient submits a claim for reimbursement to a Medicare carrier on a form known as the "HCFA 1500." The HCFA 1500 lists those services provided to a single patient and requires the doctor to provide his identification number, the patient's information, and a five-digit global billing code identifying the services for which reimbursement is sought.

The American Medical Association established these five-digit billing codes for use by physicians or other health care providers when submitting bills to their carrier for reimbursement. With respect to venous doppler studies at issue, defendant physicians used the following global billing codes: 93965, indicating non-invasive venous studies of an extremity; 93970, indicating a duplex scan of extremity veins or a complete bilateral study; and 93971, indicating a unilateral or limited study. For the significant majority of the claims at issue, defendant physicians billed the government under codes 93970 and 93971, with a "26 modifier." The 26 modifier indicates that the physician delivered solely the "professional," as distinct from the "technical" component of the test, and did not perform an integrated, or "global," service. Accordingly, when physicians submit claims for services billed with a 26 modifier, they are compensated at a lesser rate for having provided only the professional portion

of the test.

Plaintiff filed his complaint on September 3, 1997, as a qui tam[4] action under the False Claims Act, *31 U.S.C. §3729,* on behalf of the federal government. After having undertaken a review of the suit within the sixty-day statutory period, the United States notified the Court that pursuant to 31 U.S.C. §3730b(4)(B), it declined to intervene. Accordingly, throughout this opinion the Court employs the appellation "plaintiff," as opposed to "relator," because plaintiff elected to maintain the instant action on his own accord after the government declined to aid in the prosecution of the suit.[5] On February 1, 1999, the Court dismissed the two common law claims included in plaintiff's complaint, leaving the claim under the False Claims Act ("FCA") as the sole remaining theory against defendants.

The gravamen of plaintiff's complaint alleges the various defendants defrauded the government by falsely charging for services they did not provide. Specifically,

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[4] "'Qui tam' is an abbreviation for the Latin phrase 'qui tam pro domino rege quam pro si ipso in hac parte sequitur,' meaning 'Who sues on behalf of the King as well as himself.'" *United States v. Horizon Healthcare Corp.*, 160 F.3d 326, 329 n.1 (6th Cir. 1998) (quoting Black's Law Dictionary 1251 (6th ed. 1990)).

[5] For purposes of this opinion, the Court assumes the constitutionality of a plaintiff proceeding under the False Claims Act even though the government has declined to join the suit as a party. The Court notes, however, that this very question is currently before the Supreme Court in *United States of America Ex Rel. Jonathan Stevens v. State of Vermont Agency of Natural Resources,* 162 F.3d 195, *cert. granted,* 119 S. Ct. 2391 (1999).

plaintiff alleges defendant physicians did not review any hard copy data (video tape results) generated by venous ultrasound studies taken of patients suspected of suffering from DVT, where the vascular technologist or technician reported the ultrasound results as either negative or negative with abnormality. Instead, plaintiff contends the physicians merely reworded and/or plagiarized the technician's or technologist's "worksheet" to prepare a physician's ultrasound report. Defendant physicians then billed the government through Champus, Medicare or Medicaid for these "interpretations" which, according to plaintiff, constituted mere plagiarism of the worksheet prepared by the technician/technologist.

Plaintiff further alleges defendant Borgess Medical Center was aware of this fraudulent physician practice, pressured plaintiff to keep his complaints "in-house," and functioned as a co-conspirator with the physicians through its vascular panel.

II

A party seeking summary judgment must demonstrate that "there is no genuine issue as to any material fact." Fed. R. Civ. P. 56(c). *See Celotex Corp. v. Catrett,* 477 U.S. 317, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986); *Southeastern Oakland County Resource Recovery Auth. v. Madison Heights*, 5 F.3d 166 (6th Cir. 1993). "When the moving party has carried its burden under rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Electrical Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986). It must establish that there is a "genuine issue for trial." *Id.* at 587. The inquiry under a motion for

summary judgment is thus the same as that under a motion for judgment as a matter of law: "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-2, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).

III

The Court begins by reviewing the relevant sections of the False Claims Act, which provide liability for:

> (a) [. . .] Any person who--
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval . . .;
> [or]
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government . . . is liable to the United States Government for a civil penalty of not less than $ 5,000 and not more than $ 10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

§31 U.S.C. 3729 (a)(1), (2). Hence, to prevail under

§3729(a), a plaintiff must establish at least three elements[6]: first, that the defendant knowingly presented or caused to be presented a claim to the United States for payment or approval; second, that the claim was false or fraudulent; and third, that the defendant knew the claim was false or fraudulent.

A.

The parties do not dispute that defendants presented "claims" as defined under the FCA by submitting HCFA 1500 forms seeking reimbursement from Medicare. Accordingly, the Court commences its analysis with the second element of the cause of action, to determine if a genuine issue of material fact exists as to whether defendants submitted claims that were false. Defendants deny that any false or fraudulent claims, and assert they personally provided the professional component of all venous ultrasounds for which they sought reimbursement. Plaintiff disagrees, arguing defendant physicians failed to receive sufficient information to make a properly billable "interpretation" according to HCFA's Carriers Manual.

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[6] There is a split of authority as to whether a relator is required to establish that the Government has suffered damages as a result of the false claim or claims at issue. The Second Circuit affirmed an opinion holding damages constitute a necessary element under the FCA. *See Blusal Meats, Inc. v. United States*, 638 F. Supp. 824, 827 (S.D.N.Y. 1986), *aff'd*, 817 F.2d 1007 (2nd Cir. 1987), but did not address that particular issue in the appeal. Other courts, however, have found proof of damages to be unnecessary. *See, e.g., United States v. Kensington Hosp.*, 760 F. Supp. 1120, 1127 (E.D. Pa. 1991).

As a threshold question, the Court determines what law or administrative regulation governs provider services rendered in connection with venous ultrasound studies. Defendants argue HCFA's Provider Handbook, which sets forth general billing guidelines for physician services, contains no instructions specific to venous ultrasounds. Defendants further argue plaintiff's proposed authorities, including HCFA's Carriers Manual, constitute neither controlling law nor appropriate guidelines for physicians. According to defendants, the Carriers Manual dictates whether financial intermediaries should pay claims, and is not intended to guide the physician's decision to submit a claim for reimbursement. Hence, defendants assert the truth or falsity of the claims at issue should be evaluated in light of the guidelines for reimbursement of the professional component of tests set forth in the Provider Handbook and the general certification in the HCFA 1500 that all services were "medically indicated and necessary for the health of the patient" and were furnished personally or under their supervision.

In response, plaintiff acknowledges Medicare has not specifically promulgated regulations governing a physician's interpretation of venous ultrasound studies. (Pl. Orig. Br. at 1 n.4; Dkt. No. 60). Nevertheless, plaintiff contends the Medicare Carriers Manual, published by HCFA and published at 42 C.F.R. §415, impliedly governs the delivery of venous ultrasound services, and offers the affidavit of a past President of the Society of Vascular Technology to that effect. (Pl. Br. at 21; Ex. 17). Alternatively, plaintiff argues the Court should evaluate the representations made in defendant's HCFA 1500 forms in light of other HCFA regulations for billing of radiology services, x-rays and other

procedures performed by residents and attending physicians. (Pl. Br. at 21-23). Although plaintiff fails to explain which of these regulations should be viewed as controlling, he nonetheless argues the failure to comply with some or all of these regulations equates to the submission of a false claim.

Given the lack of specific billing regulations concerning venous ultrasounds, the Court is not persuaded by plaintiff's arguments. As a matter of law, the Court concludes plaintiff's position on this issue is insufficient to establish a genuine issue of material fact. Plaintiff concedes HCFA has not promulgated specific regulations relating to the submission of reimbursement claims for venous ultrasounds, but proposes the Court instead employ HCFA Carriers Manual regulations on radiology as governing venous ultrasounds. The case law makes clear, however, that the Carriers Manual is merely a guide for fiscal intermediaries between Medicare and physicians, and lacks "the binding effect of law or regulation." *National Medical Enterprises v. Bowen*, 851 F.2d 291, 293 (9th Cir. 1988). Moreover, the Carriers Manual is intended to instruct carriers as to whether to pay a claim and is not routinely provided to physicians. Indeed, by its terms the Carriers Manual does not purport to address the physician's decision to submit a claim for reimbursement, and most importantly, does not dictate whether physicians are required to review the hard copy data of venous ultrasounds. Hence, the Court declines to judge the truth or falsity of defendants' representations in light of the Carriers Manual.

In like fashion, the Court fails to find the alternative regulations proposed by plaintiff to be controlling.[7] Plaintiff has neither established that compliance with these standards is a prerequisite for reimbursement by Medicare for venous ultrasounds, nor adduced any facts to support an inference that the physicians knew or believed these regulations to be applicable to their submissions. Even if these regulations were to be held applicable, the "FCA is not an appropriate vehicle for policing technical compliance with administrative regulations." *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999). Mere violations of administrative regulations are not actionable under the FCA "unless the violator knowingly lies to the government about them." *Id.* Accordingly, the Court declines to apply these regulations to the determination of whether defendant physicians submitted false claims, and thereby unjustifiedly broaden the scope of liability under the FCA. *Accord U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1265 (9th Cir. 1996).

B.

Plaintiff nevertheless proceeds to argue that defendant physicians' claims are false even when viewed in light of the general regulations governing reimbursement for physician services set forth in the Provider Handbook.[8] At the heart of this issue lies the Provider Handbook's definition of services,

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[7] In addition to the Carriers Manual, plaintiff cites the Court to regulations including 60 C.F.R. §63142; 42 C.F.R. §§415.102, 415.120, 415.130, 1395; and 60 C.F.R. §63130-63133.

[8] Plaintiff concedes, that, "at worst," the regulations governing physicians' services in the Provider Handbook are applicable to venous ultrasounds. (Pl. Br. at 9).

which divides delivery of medical tests into two components, professional and technical. The professional component of physician delivered services is described as:

> the interpretation or reading of the results of the test performed. The professional component of a service should be billed showing the location of a patient at the time that the service was rendered. If a code showing "interpretation and report only" is not available, use the global procedure code with modifier 26.

By contrast, the technical component is described as:

> the actual performance of the test. It does not require the expertise of a physician. Normally, the office staff or hospital staff performs the technical portion of the test. If a "tracing only, without interpretation and report" is unavailable, use the global procedure code with modifier TC.

Medicare Part B Provider Handbook for Michigan, I-27 (March 1997).

The parties agree that a vascular technician/technologist would first perform ultrasounds on the patient, and then reduce the hard data results (videotape) to a worksheet, tasks comprising the technical component of service delivery. The worksheet calls for the technician to indicate the presence or absence of five risk factors for DVT. Here, however, the parties' contentions diverge. Defendants

contend the "results of the test" encompass the technician's/technologist's worksheet, which presents objective results for five factors of the test. According to plaintiff, only the videotape, photograph or other hard copy data qualify as the "results of the test." By failing to review the underlying data in each instance, plaintiff submits defendant physicians failed to "interpret or read" the "results of the test" as required by the Provider Handbook's requirement for professional services.

Noting that no regulation requires the review of such data, defendant physicians respond that the review of hard copy data is not required by the Provider Handbook's general requirements for professional services. Rather, defendant physicians claim they performed an "interpretation or reading" of the objective data provided by the technician/technologist, and then visualized, or formed a mental picture of, the patient's venous condition with regard to DVT. (Def. Br. at 11 n.7). Defendant physicians assert this procedure comports with the certification they made on the HCFA 1500 form that all services sought to be reimbursed were, "medically indicated and necessary for the health of the patient and were personally furnished" by them and squares with their practice of billing for the professional component the ultrasound test with a 26 modifier.

To plaintiff, this argument demonstrates the "absurdity and desperation of defendants' position," in that the "physician's IMAGINATION of what the patient's veins MUST HAVE looked like on the ultrasound" cannot justifiably qualify as a justifiably billable "physician service." (Pl. Br. at 3). Compounding the alleged fraud, plaintiff contends defendant physicians then would then merely adopt,

reword, or plagiarized the technician's worksheet. Because plaintiff alleges defendant physicians were not normally present during the administration of the ultrasound, he contends they lacked any first-hand knowledge of the testing. Hence, plaintiff frames the issue as whether defendant physicians were provided with sufficient information to make a "properly billable interpretation" under the Provider Handbook, raising two theories of falsity: implied false certification and actual falsehood.

C.

Plaintiff's argument concerning the adequacy of defendant physicians' interpretation first takes form as an argument for implied false certification. Contending defendants' practice amounts to "inadequate and pathetic patient care," plaintiff avers defendant physicians' procedure falls short of the standard of care by (1) failing to review the underlying data of the ultrasound studies--the photographs, prints or videotape of the ultrasounds taken by the technologist/technician; (2) assuming the accuracy of the worksheet information provided by the technician/technologist, a number of whom lack working knowledge of physics; and by (3) failing to perform an independent review of either the hard-copy data, thus increasing the risk of unnoticed interpretative error. (Pl. Br. at 13).

According to plaintiff's affidavit, defendant physicians would merely copy or reword the worksheet prepared by a technologist or technician where the ultrasound indicated the five factors were either negative for DVT or negative with abnormal indications. (Pl. Br. at 7; Pl. Ex. 18). Plaintiff

further testifies defendant physicians would assume the normalcy of the five factors tested by the ultrasound technician, and thus fail to provide any independent service. For support, plaintiff adduces the affidavits of a board certified vascular surgeon[9] and that of a director of clinical R&D at a corporation located in Seattle, WA,[10] both disagreeing with the defendants' practice. (Pl. Br. at 9, n. 17; Pl. Ex. 22; 17). By submitting claims for reimbursement that represent sub-standard care, plaintiff argues defendants impliedly presented false claims under the FCA.

Assuming for purposes of this motion that the standard of care attendant to venous ultrasound studies is accurately characterized by plaintiff and by his expert witness,[11] the

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[9] The Court notes that the curriculum vitae of plaintiff's expert, Richard Schwartz, M.D., indicates his most recent position in vascular surgery ended nearly 15 years ago in December 1985. Accordingly, although Dr. Schwartz claims in his affidavit to have been interpreting and billing for venous ultrasound studies "over the years, inclusive of 1991 to date," it is unclear from his credentials that Dr. Schwartz possesses familiarity with the present practice of venous ultrasound interpretation.

[10] The curriculum vitae of this affiant indicates he is not a physician, but a vascular technologist with a nursing degree. His opinions often amount to mere legal conclusions, and, most significantly, he lacks qualification to testify as to the process a physician undertakes to perform an interpretation of a venous ultrasound study.

[11] Plaintiff argued at the hearing on this motion that a nationwide standard of care should apply to the interpretation of venous ultrasound studies, yet offers no evidence that interpretation of venous ultrasounds amounts to a medical specialty. For purposes of this motion, however, the Court assumes the rectitude of Dr. Schwartz's characterization of the standard of care, while noting that in his affidavit, Dr. Schwarz does not claim to (1) have

Court nevertheless concludes that as a matter of law, plaintiff cannot demonstrate the falsity of defendants' claims under the FCA by proving their delivery of services fell short of the requisite standard of care. Although the Sixth Circuit has not spoken directly to this issue, the Seventh Circuit rejected a similar argument when it was presented upon similar facts in *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730 (7th Cir. 1999).

Luckey presented the question of whether the defendant was required to follow an arguably more effective and more expensive method for testing blood plasma samples. Federal regulations required the defendant to test incoming plasma units for hepatitis and human immunodeficiency virus ("HIV") before commingling the units. Baxter's normal procedure was to perform a color inspection test on every unit, but a total protein test only on those units that failed the color inspection test. Alleging Baxter should have performed the total protein test on each plasma unit to detect possible saline dilution (a situation which might render false negative tests results for HIV), the plaintiff, a former laboratory technician for the defendant, filed suit under the FCA. She argued that despite her warnings, management continued to employ the total protein test only after batches failed the color

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observed the standard of care in the relevant medical community of either the State of Michigan or Kalamazoo, Michigan, where defendant physicians practiced; (2) have himself observed the standard of care (by viewing hard copy data in each instance) in his own practice in Toledo, OH and Seattle, WA; or (3) have witnessed the physicians with whom he practiced viewing hard copy data as a matter of course when performing interpretations of venous ultrasound studies where the technician/technologist reported the results as negative or negative with abnormality.

inspection test, thus creating an increased risk that saline contamination would go unnoticed. According to the plaintiff's reasoning, each time Baxter presented a claim to the Government for payment, it impliedly certified its compliance with applicable regulations. Hence, the relator reasoned that because Baxter failed to employ the more accurate test, the tests it did perform constituted fraud.

Judge Easterbrook, writing for a unanimous panel, held for Baxter explaining that "when a supplier complies with the existing regulations, it is entitled to represent to the government (and to the world) that it has done so, without facing a claim of deception. . . . Equating 'imperfect tests' with "no tests" would strain language past the breaking point." *Luckey*, 183 F.3d at 732. *Luckey* has been interpreted to stand for the proposition that an implied false certification theory can succeed only where the defendant's compliance with statutory or regulatory authority is so essential for reimbursement that, if the government had been aware of the defendant's non-compliance, it would have refused payment. *Accord United States ex rel. Mikes v. Straus*, 84 F. Supp. 2d 427, 1999 U.S. Dist. LEXIS 18261, 1999 WL 1066863 (S.D.N.Y. 1999). *Luckey's* holding accords with the reasoning of other Courts of Appeals that have held claims that fail to meet the relevant standard of care are nevertheless insufficient to establish falsity under the FCA. *See Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1998); *see also United States ex rel. Hopper v. Anton*, 91 F.3d 1261 (9th Cir. 1996); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997). The Court finds the reasoning of these authorities quite persuasive, and concludes plaintiff cannot demonstrate a genuine issue of material fact with respect to false claims

under the FCA, even if he can demonstrate defendants' practice failed to conform to the standard of care applicable to the interpretation of venous ultrasounds.

D.

Alternately, plaintiff suggests a question of fact exists as to whether the review performed by defendant physicians received sufficient information in order to permit them to claim to have performed an interpretation of the ultrasound studies.[12] Under plaintiff's theory, defendants' claims were false because defendant physicians did not actually deliver any distinct service, having merely plagiarized the technician/technologist's worksheet. Plaintiff does not deny, however, that defendant physicians reviewed the materials--even if only to read them and regurgitate the information in a final report. Plaintiff thus argues the sufficiency of defendant's review, questioning "whether enough information is provided to Defendant physicians in order to make an 'interpretation' which is properly billable to the federal government." (Pl. Br. at 8). Hence, while plaintiff does not question whether physicians actually performed some work with regard to the venous ultrasounds, he suggests defendants practice fails to constitute an interpretation "in any reasonable

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[12] Plaintiff avers a question of fact exists as to whether the ultrasound is "binary," apparently arguing the delivery and interpretation of the ultrasound must be performed by the same provider. Plaintiff offers no support for this contention, beyond a regulation in the Carriers Manual that excludes from the definition of "physician services" any "interposition of a third person's judgment." 42 C.F.R. 1395. However, the Carriers Manual is neither governing law nor an appropriate guideline for providers, and thus cannot form the basis for a genuine issue of material fact. See Part III A., *infra*.

sense or meaning of the word." (Pl. Br. at 9)

With this argument, plaintiff attempts to distinguish Luckey by asserting that the question of whether the failure to employ a superior test equates to the lack of a test is distinct from the issue of whether defendant physicians had enough information to have justifiably claimed to have performed an "interpretation." Taken in the light most favorable to plaintiff, however, the dispute over whether defendants performed an "interpretation or reading" of the "results of the test" merely highlights the ambiguity of these undefined terms in the Provider Handbook. Accordingly, plaintiff's attempt to distinguish *Luckey* devolves to a dispute over the meaning of the terms governing the delivery of the professional component of physician services, rather than a factual claim as to whether defendants (at a minimum) actually performed some work by reading and/or reviewing work performed by the technician/technologists.

Such a legal dispute is, however, insufficient to establish falsity under the FCA. *See Hagood*, 81 F.3d at 1477. As expressed by the Seventh Circuit in *Luckey*, "Most companies in [the defendant's] position will have scientists who argue for additional precautions, and others who think that the existing precautions are enough (if not excessive)... As written, the regulations do not resolve this debate. [The defendant] had to make a decision for itself." *Luckey*, 183 F.3d at 732. Accordingly, a defendant's decision in the face of a dispute over the requirements of governing regulations is insufficient, without more, to constitute falsity. Stated another way, "an example of a false statement in an invoice in a similar context is the representation that a resident worked five days a week at a hospital when he worked only three."

Hindo v. University of Health Sciences, 65 F.3d 608, 613 (7th Cir. 1995). The record here falls fall short of this standard. Plaintiff does not dispute that, at a minimum, defendant physicians read and relied upon the technician/technologist worksheet to prepare the physician's report. From this information, sufficient or not, the physicians represented that they formed a medical judgment regarding the presence of a DVT in the patient, and tailored their delivery of health services accordingly.

IV

Having determined that plaintiff has failed to adduce sufficient facts capable of establishing the element of falsity under the case, the Court next considers the issue of scienter. To succeed under the FCA, a relator need not demonstrate specific intent to defraud the government. *See Hagood*, 929 F.2d 1416, 1421. The Act's scienter requirement is set forth in §3729(b), which requires either "'actual knowledge' that one is submitting a false or fraudulent claim for payment or approval, acts in deliberate ignorance of the truth or falsity of one's false claim, or "acts in reckless disregard of the truth or falsity of the claim.'" *Wang v. FMC Corp.*, 975 F.2d 1412, 1420 (9th Cir. 1992).

Under this standard, plaintiff must adduce facts that establish more than mere innocent mistakes or negligence on the part of defendants. *See Hindo,* 65 F.3d at 613. Furthermore, "what constitutes the offense is not intent to deceive but knowing presentation of a claim that is either fraudulent or simply false. The requisite intent is the knowing presentation of what is known to be false." *Id.* Thus, the

Court inquires whether the record supports an inference that defendant physicians' practice with regard to interpretation of venous ultrasound studies amounts to deliberate ignorance of, or reckless disregard for, applicable guidelines for submission of claims for venous ultrasounds with a 26 modifier.

The Court begins by first asking whether defendants proceeded in reckless disregard of applicable billing regulations. Plaintiff offers the affidavit of an independent government health insurance consultant testifying that, in his experience, physicians are familiar with HCFA regulations surrounding the delivery of ultrasound studies, and that the Carriers Manual regulations are applicable to venous ultrasounds. (Pl. Ex. 16). This testimony is insufficient to create an inference of reckless disregard on the part of defendants, however, because the reckless disregard must be of applicable regulations to the submission of claims. The first opinion expressed by the expert relates to the familiarity of physicians with billing regulations not expressly related to venous ultrasound studies, which the Court holds inapplicable to this action in the analysis of Part III A., *infra*. The second opinion offered by plaintiff's expert constitutes a legal conclusion that only the Court is competent to offer. Hence, plaintiff has not met his burden to adduce facts creating an inference of reckless disregard.

In addition, plaintiff's showing falls short of creating an inference of deliberate ignorance. Plaintiff offers his affidavit testimony that internal discussions occurred that indicated defendant physicians' awareness that their claims rested upon uncertain ground, and that only Dr. Jain investigated what regulations actually govern the

interpretation of venous ultrasounds. (Pl. Ex. 18). However, plaintiff concedes that on at least three occasions defendant Jain contacted HCFA, including a Freedom of Information Act request, seeking any "published guidelines specific to procedures 93970-93971 with a 26 modifier." (Pl. Ex. 7). The answer defendant Jain received: "we have no published guidelines specific to procedures 93970-93971 with a 26 modifier," does not give rise to an inference of either deliberate indifference or reckless disregard. (Pl. Ex. 7). Rather, it reinforces the Court's conclusion that the general regulations applicable to physicians' services are the only appropriate standard with which to judge defendant physicians' billing practice. Moreover, the evidence of internal discussions plaintiff points to cuts against his argument that defendant physicians were deliberately ignorant, and instead suggests defendants evinced concern and investigated the question of what procedures were required to submit a proper claim for reimbursement.

V

In conclusion, plaintiff's disagreement with the qualitative nature and degree of review necessary for defendant physicians to claim to "interpret" the technical component of a venous ultrasound study and then bill the government for the professional component fails to amount to either a false claim or a knowingly false claim under the FCA. Plaintiff's theory contending that claims billed to the government for interpretations of venous ultrasound studies performed by technicians constitute fraud because defendant physicians allegedly delivered services falling short of what plaintiff surmises is required under the appropriate standard of care is insufficient, without more, to establish falsity under

the FCA. Similarly, plaintiff's position that defendant physicians lacked sufficient information to make a properly billable interpretation devolves to a legal dispute incapable of demonstrating the falsity of defendant physicians' claims as falsity has been construed by authorities persuasive to this Court. Moreover, even were plaintiff to succeed in demonstrating that defendants submitted false claims because they did not review the underlying hard copy data from the studies, the record fails to establish that defendants acted either in deliberate indifference or reckless disregard of the truth of the claims.

If in fact the HCFA regulations applicable to physician providers overcompensate them for the services they actually provide in conjunction with the professional component of venous ultrasound studies, or, as plaintiff alleges, a higher standard of patient care would result by requiring physicians to review hard copy data as a prerequisite to submitting claims for reimbursement, the appropriate remedy is either to convince the government to reduce the compensation paid for such services or to modify the regulations governing provider reimbursement, rather than filing suit under the False Claims Act. Plaintiff thus requests the Court to grant him relief that both the case law and the record indicate must be found elsewhere, if appropriate. Accordingly, summary judgment will be entered in favor of defendants.

Dated: February 18, 2000

s/s_____
DAVID W. McKEAGUE
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

No. 4:97-cv-116
[Filed February 18, 2000]

United States of America, Ex Rel. Jack Obeydean Swafford, a/k/a Dean J. Swafford,
Plaintiffs,
v.

Borgess Medical Center, a Nonprofit Michigan Corporation, Bronson Methodist Hospital, a Nonprofit Corporation, Advanced Vascular Surgery, P.C., a Michigan Professional Corporation, Krishna Jain, M.D., John Munn, M.D., Eugene Simoni, M.D., John T. Collins, Jr., M.D., and Randy Smejkal, M.D., James Mclaren, M.D., Healthcare Midwest General & Vascular Surgeons, a/k/a Healthcare Midwest, P.C., a Michigan Corporation, Mark Tagett, M.D., Philip Borozan, M.D., Solomon K. Samuels, M.D., P.C., a Michigan Corporation, Solomon K. Samuels, M.D., Padraic Carmody, M.D., Karim Abedel Abushmaies, M.D.,and M. Abidur Rahman, M.d., Jointly and Severally,
Defendants.

JUDGES:
DAVID W. McKEAGUE,
UNITED STATES DISTRICT JUDGE.

OPINIONBY:
DAVID W. McKEAGUE

ORDER

In accordance with the Court's opinion of even date, **IT IS HEREBY ORDERED** that defendants' motions for summary judgment on plaintiff's claim under the False Claims Act are hereby **GRANTED.**

IT IS FURTHER ORDERED that **JUDGMENT IS AWARDED** in favor of defendants and against plaintiff in this case.

Dated: February 18, 2000

/s/_____
DAVID W. McKEAGUE
UNITED STATES DISTRICT JUDGE

APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

No. 4:97-cv-116
[Filed December 12, 2001]

United States of America, Ex Rel. Jack Obeydean Swafford, a/k/a Dean J. Swafford,
Plaintiff-Appellant,
v.

Borgess Medical Center, a nonprofit Michigan corporation; Advanced Vascular Surgery, P.C., a Michigan professional corporation, Jain Krishna, M.D.; John Munn, M.D.; Eugene Simoni, M.D.; John T. Collins, Jr., M.D. and Randy Smejkal, M.D., P.C., Jr., M.D., a Michigan corporation; John T. Collins, Jr., M.D.; Randy Smejkal, M.D.; James Mclaren, M.D.; Healthcare Midwest General & Surgeons, also known as Healthcare Midwest, P.C., a Michigan corporation; Mark Tagett, M.D.; Philip Borozan, M.D.; Solomon K. Samuels, M.D., P.C., a Michigan corporation; Solomon K. Samuels; Padraic Carmody, M.D.; Vascular Specialists, P.C., a Michigan corporation; Karim Abedel Abushmaies, M.D.; M. Abidur Rahman, M.D., jointly and severally,
Defendants-appellees,

and)
)
Bronson Methodist Hospital, a Nonprofit)
Corporation,)
Defendant.)
_____)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MICHIGAN

JUDGES:
Before: BOGGS, DAUGHTREY, and FARRIS,* Circuit Judges.

OPINION

PER CURIAM:

Jack Obeydean Swafford, a/k/a Dean J. Swafford, appeals the district court's summary judgment of his qui tam complaint against defendants, under the False Claims Act, 31 U.S.C. §3729, on behalf of the federal government. We review de novo the district court's grant of summary judgment. *See Campbell v. Grand Trunk W. Ry. Co.*, 238 F.3d 772, 775 (6th Cir. 2001). We affirm for the reasons stated in the district court's opinion.

On the record before us, we find no error in the granting of summary judgment:

1) Services falling below a requisite standard of care,

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* The Honorable Jerome Farris, Circuit Judge for the United States Court of Appeals for the Ninth Circuit, sitting by designation.

without more, is insufficient to state a claim for government reimbursement of venous ultrasound testing services. *See, e.g., Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996).

2) The venous ultrasound reports were not knowingly fraudulent. *See, e.g., Hindo v. University of Health Sciences*, 65 F.3d 608, 613 (7th Cir. 1995).

3) Disputes as to the interpretation of regulations do not implicate False Claims Act liability. *See, e.g., Hagood*, 81 F.3d at 1477.

AFFIRMED.

APPENDIX C

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN

No. 4:97-cv-116

[Filed August 10, 1998]

United States of America, Ex Rel.)
Jack Obeydean Swafford, a/k/a)
Dean J. Swafford,)
Plaintiffs,)
v.)
Borgess Medical Center, a nonprofit Michigan)
Corporation, Bronson Methodist Hospital, a)
nonprofit Corporation, Advanced Vascular)
Surgery, P.C., a Michigan professional)
corporation, Krishna Jain, M.D., John Munn,)
M.D., Eugene Simoni, M.D., John T. Collins,)
Jr., M.D., and Randy Smejkal, M.D., P.C., a)
Michigan corporation, John T. Collins, J.R.)
M.D., Randy Smejkal, M.D., James Mclaren,)
M.D., Healthcare Midwest General & Vascular)
Surgeons, a/k/a Healthcare Midwest, P.C., a)
Michigan Corporation, Mark Tagett, M.D., Philip)
Borozan, M.D., Solomon K. Samuels, M.D.,)
P.C., a Michigan corporation, Solomon K.)
Samuels, M.D., Padraic Carmody, M.D., Karim)
Abedel Abushmaies, M.D.,and M. Abidur)
Rahman, M.D., Jointly and Severally,)

Defendants.)
_____)

JUDGE: Hon. Richard A. Enslen

AFFIDAVIT OF KRISHNA.. JAIN, M.D.

I, Krishna Jain, M.D., make these statements of my own personal knowledge and if called upon, can testify to the troth and accuracy of the facts stated below:

1. I am a physician certified in the specialty of vascular surgery. I have also been an officer of Defendant Advanced Vascular Surgery, P.C.

2. I have privileges, practice, and serve as a member of the vascular panels, at both Bronson Methodist Hospital and Borgess Medical Center. As a result, I have personal knowledge of the procedures and policies related to the interpretation or reading of the results of Venous Ultrasound Studies (a/k/a Extremity Venous Studies in the "Current Physicians Terminology, ("CPT" manual).

3. The protocol for performing Venous Ultrasound Studies has been developed by all of the persons involved in the testing process, including the doctors, the hospitals, and the technologists. During the course of such studies, many characteristics of the veins are evaluated through an ultrasound examination. These characteristics include such things as "spontaneity,' "phasicity," "augmentation response", "compressibility," and "competence." When a test is completed, the vascular technologist records his or her observations on a worksheet,

which then is provided to and reviewed by the doctor.

4. In the case of a study evidencing some positive or abnormal findings, the doctor may recommend additional tests or treatment. In the case of a negative study, the doctor, after interpreting or reading the results of the study, will dictate a report of his findings, review the report, and sign it.

5. Venous Ultrasound Studies are billed in accordance with guidelines found in CPT manual. Specifically, the doctors bill under CPT codes 93970 (duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study) and 93971 (unilateral or limited study).[1] However, the doctors *bill* only for a "professional component of the test." This is indicated by the use of a "26 modifier." The 26 modifier indicates that the doctor performed an "interpretation or reading" of the result of the test. Use of the 26 modifier results in a substantially lower rate of reimbursement than if the total study were to be performed in the physician's office (in which case a global code embracing both the technical and professional components would be available for use).

6. On July 2, 1998, I sent a Freedom of Information Act request to Health Care Services Corporation Intermediary for HCFA in Michigan inquiring as to whether

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[1] An additional code, 93965, relates to the venous system but these days is used only with respect to an examination of venous reflux using ultrasound. It has not been used for many years to rule out DVT. Its usefulness waned with the advent of the ultrasound technology to diagnose Deep Venous Thrombosis under 93970 and 9397 I.

there were any published guidelines for the interpretation and reporting of Venous studies (CPT 93970-93971), with a 26 modifier. Subsequently, I received correspondence dated July 9, 1998 from Diane Hall at HCSC indicating that there are no published guidelines specific to procedures 93970-93971 with a 26 modifier. A true copy of this correspondence is attached to Defendant's brief as Exhibit D.

7. Plaintiff has alleged that the defendant doctors do not review videotapes of negative studies at all. I wish to make Clear that there are times When the doctors will review the videotapes of negative studies. This occurs, for example, when the doctor is training a technologist, or when a new technologist is hired whose capabilities are not fully known to the doctor, or when there may have been a problem visualizing an area during the test, or for other reasons in the individual doctor's discretion. Videotapes of negative studies are also reviewed randomly for quality assurance, and are also reviewed if a patient returns in a short time for a second venous study in order to ensure that nothing was missed during the first study.

FURTHER AFFIANT SAYETH NOT.

/s/_____
Krishna Jain, M.D.

Subscribed and sworn before
me this 10th day of August, 1998.
/s/_____
Notary Public
Kalamazoo County, MI
My commission expires: 7/9/2000

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN

No. 4:97-cv-116

[Filed November 24, 1998]

United States of America, Ex Rel. Jack Obeydean Swafford, a/k/a Dean J. Swafford, Plaintiffs,	)
v.	)
Borgess Medical Center, a nonprofit Michigan Corporation, Bronson Methodist Hospital, a nonprofit Corporation, Advanced Vascular Surgery, P.C., a Michigan professional corporation, Krishna Jain, M.D., John Munn, M.D., Eugene Simoni, M.D., John T. Collins, Jr., M.D., and Randy Smejkal, M.D., James Mclaren, M.D., Healthcare Midwest General & Vascular Surgeons, a/k/a Healthcare Midwest, P.C., a Michigan Corporation, Mark Tagett, M.D., Philip Borozan, M.D., Solomon K. Samuels, M.D., P.C., a Michigan corporation, Solomon K. Samuels, M.D., Padraic Carmody, M.D., Karim Abedel Abushmaies, M.D.,and M. Abidur Rahman, M.D., Jointly and Severally, Defendants.	)

JUDGE: Hon. David W. McKeague

AFFIDAVIT OF PHILIP BOROZAN, M.D.

Affidavit of Philip Borozan, M.D. - 11/24/98

STATE OF MICHIGAN)
COUNTY OF _____)

PHILIP BOROZAN, M.D,, deposes and says:

1. I make this affidavit on personal knowledge, and am competent to testify to the facts stated herein, if called as a witness.

2. I understand that Bronson Methodist Hospital is unwilling to provide a sample of worksheets completed by technologists and the accompanying reports of physicians concerning studies performed through the hospital's peripheral vascular lab.

3. As a result, Dr. Tagett and I were unable to obtain an extensive sample of the worksheets and reports of studies conducted through the lab.

4. The worksheets for the studies are generally kept by the hospital, and our office does not generally retain the worksheets. We were able to obtain two worksheets and the accompanying requisition sheets and reports for two patients.

5. One set of documentation relates to a study I read for a particular patient, and the other relates to a study that Dr. Tagett read for a separate patient. These worksheets and documentation are attached hereto respectively as Exhibits A and B.

6. In each of these instances, the worksheet contains the signs and symptoms the patient may be

experiencing at the time of the ordering of the study. The results of the tests are noted in the findings of the technologists on the worksheets. These results and findings are predicated on detailed protocols that were developed so that established and uniform procedures would be applied by the technologists for every vascular study performed at the Bronson lab. Copies of protocols applicable during relevant times are attached hereto as Exhibits C and D.

7. The protocols require the technologist to evaluate objective criteria relating to the veins such as "phasicity," "compressibility," "augmentation," and "spontaneity." The physicians perform the reading or interpretation of the results of the studies with the understanding of the protocols and procedures applied by the technologists. In addition, Dr. Tagett and I are available for consultation with the technologists if questions or issues arise on the studies that we are to read, and we frequently provide such consultation.

8. Based on our understanding of the applicable protocols, communications with the technologist, and the results of the study as reflected in the worksheets, we dictate our report that contains our reading and/or findings of the tests.

Further, Affiant saith not

/s/_____
PHILIP BOROZAN, M.D.

Subscribed and sworn to before me this 24th day of November, 1998.

/s/_____
Notary Public
Kalamazoo County, Michigan
My Commission Expires 5/28/03

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN

No. 4:97-cv-116

[Filed September 28, 1998]

United States of America, Ex Rel.)
Jack Obeydean Swafford, a/k/a)
Dean J. Swafford,)
Plaintiffs,)
v.)
Borgess Medical Center, a nonprofit Michigan)
Corporation, Bronson Methodist Hospital, a)
nonprofit Corporation, Advanced Vascular)
Surgery, P.C., a Michigan professional)
corporation, Krishna Jain, M.D., John Munn,)
M.D., Eugene Simoni, M.D., John T. Collins,)
Jr., M.D., and Randy Smejkal, M.D., James)
Mclaren, M.D., Healthcare Midwest General &)
Vascular Surgeons, a/k/a Healthcare Midwest,)
P.C., a Michigan Corporation, Mark Tagett,)
M.D., Philip Borozan, M.D., Solomon K.)
Samuels, M.D., P.C., a Michigan corporation,)
Solomon K. Samuels, M.D., Padraic Carmody,)
M.D., Karim Abedel Abushmaies, M.D.,and)
M. Abidur Rahman, M.D., Jointly and Severally,)
Defendants.)
)

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101 North Main Street, 7th Floor
Ann Arbor, Michigan 48104
(734) 663-2445

AFFIDAVIT OF PHILIP BOROZAN M.D.

1. I make this affidavit on personal knowledge and am competent to testify to the facts stated herein, if called as a witness.

2. The performance of a complete venous doppler study always includes the performance of a "technical component" and a "professional component." One without the other is incomplete and of no clinical benefit. A venous doppler study does not result in an ultimate clinical benefit to a patient until both components ofthe study are completed and reported to the referring physician.

3. When venous doppler studies are performed at Borgess or Bronson Hospitals, the "technical component" is performed by technicians/technologists employed by the hospital.

4. Dr. Tagget and I do not bill for or receive any reimbursement of any kind for the "technical component" of venous doppler studies performed at the hospitals.

5. Along with other vascular surgeons who have been granted appropriate privileges by the hospitals, Dr. Tagget and I perform the "professional component" of venous doppler studies.

6. The "professional component" of a venous doppler study consists of reading and interpreting the data, information and results obtained by the technician/technologist during the performance of the "technical component" of the study and integrating that information with any other available clinical information to reach a conclusion as to the results and reliability of the study and to render professional clinical advice, if requested.

7. In order to read and interpret a venous doppler study, it is necessary to know whether the visualized veins exhibit: (1) spontaneous flow, (2) augmentation, (3) phasicity, and (4) compressibility. In the studies I read and interpret at Borgess and Bronson Hospitals, this information is always provided, or the technician/technologist notes on his or her worksheet that certain information could not be obtained (e.g., failure to visualize a vein or veins adequately due to obesity, placement of a cast, etc.).

8. The technicians/technologists at both Borgess and Bronson Hospitals universally follow strict protocols in the performance of the "technical component" of venous doppler studies. These protocols have been established by the interpreting vascular surgeons to ensure that all data and

information required for the reading and interpretation of each venous doppler study is obtained by the technician/technologist. These protocols conform to widely accepted national guidelines and standards.

9. Because of the strict protocols that the technicians/technologists are required to follow when performing venous doppler studies, the interpreting vascular surgeons are able to determine, from the information provided by the technicians/technologists, whether the four venous criteria necessary for a negative interpretation of a venous doppler study are present. This is the case whether the particular worksheet includes a chart, a checklist, or simply contains the data in summary form (e.g., "all veins are patent").

10. The training of the technicians/technologists and the protocols for venous doppler studies have been specifically designed to make the collection of data by the technicians/technologists a binary operation. For example, the vein either compresses or it does not; there is no intermediate possibility. Only if all four normal criteria are present in all veins will the technician/technologist reach a preliminary impression that the study is negative.

11. As in many other areas of medicine, Dr. Tagget and I, as interpreting physicians, rely on the information provided to us by the technicians/technologists. For example, when we are in surgery, we rely on instrument and sponge counts that are performed by nurses and operating room technicians and we do not independently confirm the counts. In the case of venous doppler studies, this reliance is entirely reasonable because we (1) participate in the training

of the technicians/technologists, (2) require strict adherence to rigid protocols for data collection by the technicians/technologists, (3) participate in quality assurance activities, and (4) work collaboratively with the technicians/technologists on an ongoing basis.

12. Upon completion of the "technical component" of a venous doppler study, the technician/technologist places the file containing the data collected according to the protocol, relevant clinical history and physical findings when available, and reports of previous studies when available in the interpreting physician's in-box.

13. As a general rule, when I go to the vascular laboratory to read vascular studies, there will be a Wide variety of studies in my in-box - arterial vs. venous, negative vs. positive, upper extremity vs. lower extremity, carotid artery vs. peripheral artery, etc. It is my function as an interpreting physician to carefully review each and every file and, after reviewing all data contained therein, to render a professional interpretation of the study (the "professional component" of the test). Some of the studies will ultimately be interpreted as positive, some as negative. It may be my recommendation that the study be repeated. In all cases, I carefully review/all the data/and available information in the patient's file prior to reaching a final conclusion as to the study and making clinical recommendations, if any.

14. With knowledge of the data and results obtained during performance of the "technical component" of the study, indicating whether the four relevant criteria are positive or negative as to the visualized veins, qualified vascular surgeons, such as Dr. Tagget and myself, are able to

independently read and interpret these results and render a final interpretation of the study (i.e., perform the "professional component" of the study). We then dictate and ultimately sign a final report. The venous doppler study is then complete.

15. In all cases, I carefully review the technician's/technologist's worksheet and preliminary impression, if any, and any other materials in the file (e.g., additional clinical information, previous studies, etc.) for any possible reason to question the reliability of my final conclusion as to the results of the study.

16. It is not necessary for us, as interpreting physicians, to routinely view pictures or videotape of negative studies when we have obtained the critical data (the four objective criteria) through the technicians/technologists who we know have followed a strict protocol.

17. Viewing still pictures of negative studies, in the absence of an incidental finding unrelated to the venous system, is of no benefit because, in the case of a normal venous system, a living, dynamic system is being evaluated during the study and such a dynamic system simply cannot be portrayed in still pictures, no matter the number. Rather, the appropriate data is obtained during the study by the technician/technologist and provided to us in one of various formats, all consistent with rigid, standardized protocols that conform to national guidelines and standards.

18. Viewing entire videotapes of bilateral studies which last, on average, approximately 20 minutes, and can last as long as 30-40 minutes, is unnecessary when we are

provided the required data and information by the technicians/technologists through the worksheets. To my knowledge, nowhere in the country do interpreting physicians routinely view entire videotapes of negative studies.

19. While review of the data, as to the four objective criteria, obtained by the technician/technologist during the performance of the "technical component" of a study is the only information required to read a venous doppler study, we, as interpreting physicians, look further and do more.

20. In all cases, to the best of my knowledge, I carefully examine the patient's file for additional history or other clinical information that might influence my final recommendations to the referring physician (e.g., previous history of deep venous thrombosis, previous history of pulmonary embolism, current symptoms suggestive of pulmonary embolism, etc.).

21. In all cases, to the best of my knowledge, I carefully examine the patient's file for previous studies that might influence my final recommendations to the referring physician. If previous studies are included in the patient's file, I review those results prior to rendering a final interpretation in the present study.

22. In some cases, I am contacted directly by the referring physician prior to the study. In such cases the referring physician may provide me with additional clinical information (e.g., history of previous deep venous thrombosis, known blood clotting disorders increasing the likelihood of deep venous thrombosis, etc.) that I later

correlate with the results of the study prior to reaching my ultimate clinical conclusion. Only then do I make a final professional clinical recommendation to the referring physician.

23. In some cases, I speak directly to the referring physician during or after my interpretation of the study in order to provide immediate, direct feedback to the referring physician.

24. In some cases, whether the study is positive or negative as to deep venous thrombosis, there will be additional observations or findings by the technician/technologist. I review all files for such incidental findings and then, after exercising my judgment as a board certified vascular surgeon, reach a conclusion as to the clinical significance of such findings. If it is my judgment that such findings have any clinical significance, I note them in my final report to the referring physician and, when appropriate, make recommendations regarding clinical care (e.g., repeat of the study at a future date). *(See* Appendix A for examples.)

25. In some cases, after reviewing the data collected by the technician/technologist during performance of the "technical component" of the study, the exercise of my clinical judgment in reading and interpreting the data provided prompts me to make clinical recommendations (e.g., consideration of an alternative form of imaging, repeat of the study in a specified number of days, etc.). *(See* Appendix B for examples.) Such recommendations are part of the "professional component" of the study and, absent a qualified physician's reading and interpretation of the study, cannot be made.

26. After my personal interpretation of the objective data obtained by the technician/technologist, and integration of any ancillary information that I find on review of the patient's file or in my discussion with the referring physician, I am able to render a professional opinion as to the result of the study, its clinical reliability, and make clinical recommendations to the referring physician. It is only after I have rendered my professional opinion and made my clinical recommendations, if any, that the patient has received a complete clinical service. Up until that point, the study is incomplete. Only after I have added the "professional component" to the teehnieian's/teehnologist's "technical component" is the study complete.

27. The "professional component" of the study can only be provided by a properly trained and credentialed physician such as myself. A technician/technologist is not trained, qualified, privileged, or licensed to perform this service and does not do so.

28. While it is not our practice to routinely view videotapes of negative venous doppler studies, in some cases we do view the videotape of a negative study (e.g., if requested to do so by the technician/technologist, quality assurance purposes, etc.).

29. I do not specifically note in my reports that I have viewed a videotape and I am unable to recall specifically which videotapes I have viewed making it impossible for me, or anyone else, to know whether a specific patient's videotape was viewed.

30. My HCFA Form 1500 certifications that the services I provided as to the reading and interpretation of venous doppler studies ("professional component" billed with the 26-modifier) were "medically indicated and necessary for the health of the patient and were personally furnished by me" is true and accurate. For each and every claim submitted by me, I have performed a complete reading and/or interpretation based upon the raw data collected by the technician/technologist. To the best of my knowledge and belief, this has also been the practice, at all relevant times hereto, of Dr. Taggett.

31. To the best of my knowledge and belief, Dr. Tagget has never read and/or interpreted venous ultrasound studies at Borgess Hospital.

Further, affiant saith not.

/s/_____
Philip Borozan, M.D.

Subscribed and sworn to before me
this 28th day of September, 1999.

/s/_____
Notary Public, Kalamazoo County, Michigan
My Commission Expires: 5/28/03

APPENDIX D

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN

No. 4:97-cv-116
[Filed March 29, 1999]

United States of America, Ex Rel.)
Jack Obeydean Swafford, a/k/a)
Dean J. Swafford,)
Plaintiffs,)
v.)
Borgess Medical Center, a nonprofit Michigan)
Corporation, Bronson Methodist Hospital, a)
nonprofit Corporation, Advanced Vascular)
Surgery, P.C., a Michigan professional)
corporation, Krishna Jain, M.D., John Munn,)
M.D., Eugene Simoni, M.D., John T. Collins,)
Jr., M.D., and Randy Smejkal, M.D., P.C., a)
Michigan corporation, John T. Collins, J.R.)
M.D., Randy Smejkal, M.D., James Mclaren,)
M.D., Healthcare Midwest General & Vascular)
Surgeons, a/k/a Healthcare Midwest, P.C., a)
Michigan Corporation, Mark Tagett, M.D., Philip)
Borozan, M.D., Solomon K. Samuels, M.D.,)
P.C., a Michigan corporation, Solomon K.)
Samuels, M.D., Padraic Carmody, M.D., Karim)
Abedel Abushmaies, M.D.,and M. Abidur)
Rahman, M.D., Jointly and Severally,)
Defendants.)
)

ORDER

At a session of said Court, held in said District and Division on the ___ day of March, 1999

PRESENT: HON. DAVID W. McKEAGUE, UNITED STATES DISTRICT JUDGE

The parties, by their respective attorneys, having reached agreement concerning the scope and nature of initial discovery in this action, the Court having approved of that agreement, and the Court being fully advised in the premises;

NOW, THEREFORE, IT IS HEREBY ORDERED AS FOLLOWS:

1. A period of initial discovery shall take place in the above-entitled action, as set forth herein. This agreement as to the scope of this initial discovery effort shall be without prejudice to the right of any party to argue the legal standards that may be applicable to a determination of any of the issues in this case. It is the general claim of the Defendants that the issues for the Court's preliminary determination following this period of initial discovery include whether the Defendant-physicians provided any service of value or value added to the patient as a result of reading or interpreting the test results of patients undergoing venous ultrasound studies (as generally alleged in plaintiff's complaint), which studies were "negative." It is the general claim of the Plaintiff that the issues for the Court's preliminary determination following this period of initial discovery include the issue of whether the Defendant-physicians independently interpreted venous ultrasound studies reported as "negative" as reflected in the

technician/technologist's worksheet.

2. Records shall be produced and made available to the parties, as follows:

a. Borgess Medical Center ("Borgess") shall produce a sample[1] of peripheral venous study records, as follows:

i. Peripheral venous studies with "negative" results, and billed to government insurance programs (such as Medicare, Medicaid and Champus) will be produced by Borgess, for the period between August 29, 1987 and December 1, 1991, as agreed upon between the Plaintiff and Borgess.

ii. Borgess will also produce a sample of peripheral venous studies for the period beginning December 1, 1991 and continuing through July 27, 1997, with the sampling process to be conducted generally as follows:

(1) For each year, Borgess will prepare and produce a list of all known patients

---

[1] Borgess also performed peripheral venous studies at its Woodbridge facility. Because of the limited number of studies performed at its Woodbridge facility, Borgess will produce copies of all Woodbridge-based studies billed to government insurance programs (such as Medicare, Medicaid and Champus), in addition to the sample of hospital based studies discussed herein.

undergoing such studies. For periods when billing records are available this list will be cross-referenced with payment information so that the list will include only procedures billed to government insurance programs (such as Medicare, Medicaid and Champus). For any periods when billing records are not available, all patients will be included in such lists.[2]

(2) A random sample of patient records shall then be produced for each year, at Plaintiff's expense, with the size and scope of the sample being as agreed upon between the Plaintiff and Borgess. The Plaintiff shall be given a reasonable opportunity to inspect all such records prior to determining the size and scope of the sample to be produced.

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[2] Borgess Medical Center is unaware of the existence of a complete database or list that would identify such patients for the period prior to December 1, 1991.

> (3) The Defendant/ Physicians may obtain the further production of such records as they may deem appropriate, at Defendant/ Physicians' expense, to supplement the records obtained by the Plaintiff, as aforesaid. The Defendant/ Physicians shall also be given a reasonable opportunity to inspect all such records to determine if any supplemental production of records should occur.

b. Plaintiff may obtain from Bronson Methodist Hospital ("Bronson"), at Plaintiff's expense, a similar sample of any documents that the Plaintiff may require or seek to rely upon, by subpoena or other process, subject to a determination by the Court as to any objections that may be raised by Bronson in response to any such subpoena or request. The Defendant/Physicians, at their expense, may obtain the further production of such records from Bronson as they may deem appropriate to supplement the records obtained by the Plaintiff from Bronson, as aforesaid.

c. Advanced Vascular Surgery[3] ("AVS") shall provide a random sample consisting of twenty (20) peripheral venous studies with "negative" results for the

---

[3] Drs. Jain, Simoni and Munn practice at Advanced Vascular Surgery.

period between August 29, 1987, to date. With respect to the production of records by AVS, AVS may elect to:

> i. Allow Plaintiff a reasonable opportunity to inspect the records from which the sample will be obtained and determine a reasonable method by which the sample shall be obtained, in which case the Plaintiff shall pay the reasonable costs incurred by AVS with respect to producing and copying the records constituting the sample; or
>
> ii. Determine a reasonable method by which the sample shall be obtained (without prior review by the Plaintiff of the records from which the sample shall be obtained), in which ease AVS shall be not be entitled to reimbursement by the Plaintiff of the costs incurred by AVS with respect to producing and copying the records constituting the sample.

d. Vascular Health Center[4] ("Vascular Health") shall provide a random sample consisting of twenty (20) peripheral venous studies with "negative" results for the period between August 29, 1987, to date, which sample shall be derived from those records currently available to Vascular Health. With respect to the production of records by Vascular Health, Vascular Health may elect to:

---

[4] Drs. Rahman and Abushmaies practice at Vascular Health Center.

i. Allow Plaintiff a reasonable opportunity to inspect the records from which the sample will be obtained and determine a reasonable method by which the sample shall be obtained, in which case the Plaintiff shall pay the reasonable costs incurred by Vascular Health with respect to producing and copying the records constituting the sample; or

ii. Determine a reasonable method by which the sample shall be obtained (without prior review by the Plaintiff of the records from which the sample shall be obtained), in which case Vascular Health shall be not be entitled to reimbursement by the Plaintiff of the costs incurred by Vascular Health with respect to producing and copying the records constituting the sample.

e. The production of records pursuant to this order shall be without prejudice to any future motion or request that may be filed by the Plaintiff or Defendants seeking the further production of documents by any party or non-party to this action, nor shall it constitute a waiver of any objections or opposition that may be made with respect to the production of records pursuant to this order or any further production that may be sought.

f. Except for the patient number, all patient name and other identifying information will be redacted from the records prior to their production. In all other respects, the entire vascular laboratory record for each patient will be produced, it being intended that the document

production shall include all documents presently existing in the record that would have been available to and/or used by the physician responsible for reading or interpreting the results of each test.

3. Borgess and each of the Defendant/Physicians shall provide the Plaintiff with the names of all vascular technicians currently employed by each such defendant, and the names and addresses (if known) of all vascular technicians formerly employed by each such defendant, from 1991 until the present.

4. During this initial discovery period, the Plaintiff shall be entitled to take:

a. Not more than three (3) depositions of Defendant/Physicians (as selected by the Plaintiff) who have participated as members of the Borgess Vascular Panel; and,

b. Not more than three (3) depositions of Defendant/Physicians (as selected by the Plaintiff) who have participated as members of the Bronson Vascular Panel; and,

c. Not more than three (3) depositions of vascular technicians (as selected by the Plaintiff) who are currently employed by Borgess; and,

d. Not more than three (3) depositions of vascular technicians (as selected by the Plaintiff) who are currently employed by Bronson. This provision shall be without prejudice to any further request by the Plaintiff, upon an appropriate showing, seeking additional depositions of vascular technicians currently employed by any of the

Defendant/Physician's independent office laboratories, either by agreement of the parties or further order of the Court. All depositions shall take place at a time and place reasonably agreed upon by the parties, after the production of documents has been completed.

5. This initial discovery period shall be completed not later than June 29, 1999, or as otherwise ordered by the Court.

6. On or before July 29, 1999 (or as otherwise ordered by the Court) the Defendants may file with the Court such motions under Federal Rules of Civil Procedure 12 and/or 56 as they believe to be appropriate based on the allegations set forth in Plaintiff's Complaint or discovery obtained during this initial discovery period.

/s/_____
Hon. David W. McKeague
UNITED STATES DISTRICT JUDGE

Dated: March 29, 1999

Approved for entry:

Dated: 3/26/99

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APPENDIX E

BRONSON METHODIST HOSPITAL
PERIPHERAL VASCULAR LAB
VENOUS ULTRASOUND EXAM

NAME:_____ HOSP. #:_____

DATE: 3/18/97 DOB: 8/31/21 AGE:_____ SEX: F

REQUESTING
PHYSICIAN: White, Todd OP + IP:_____ RM #: ___

ATTENDING PHYSICIAN: _____

ADMITTING PHYSICIAN: _____

ASSESSMENT:

___ UE	+ EDEMA*
+ ERYTHEMA*	___ INFLAMMATION*
+ LE	___ PRE OP
___ HEMOPTYSIS *	___ RECURRENT DVT*
___ UNI	___ POST OP
+ TENDERNESS*	___ VARICOSE VEINS

+ BIL ___ DYSPNEA*

___ CHEST PAIN* ___ SX DURATION

OTHER: Sore on back of calves 1 mth

FINDINGS: Bil LE venous imaging from CFV's down to infrapop vessels show good flow augmentations & compressions. Incidental finding of the L groin shows an enlarged lymph node.

Neg for acute DVT.

TECHNICIAN: /s/_____
Roberta B.P.

BRONSON METHODIST HOSPITAL
KALAMAZOO, MICHIGAN

CARDIOVASCULAR LAB
341-7745

HOSPITAL NO:
ROOM NO: OP
AGE: 75 SEX: F

DATE OF PROCEDURE: 03/18/97
ADMITTING DIAGNOSIS: Bilateral leg pain.
ATTENDING PHYSICIAN: Todd White, M.D.
REQUESTING PHYSICIAN: Todd White, M.D.
REPORTING PHYSICIAN: John S. Munn, M.D.

PROCEDURE: Venous ultrasound imaging of bilateral lower extremities.

CLINICAL DATA: Leg swelling, erythema, and tenderness.

Color flow Doppler imaging was carried out on the deep veins of both legs. Common, superficial, and deep femoral veins all appear to be patent. They exhibit normal flow. They compress nicely and have good Doppler flow. Popliteal and distal veins also appear to be patent. They augment well and have normal compressibility. There is an enlarged lymph node noted in the
left groin.

IMPRESSION: Negative for deep venous thrombosis both legs. Evidence of inguinal adenopathy is present on the left.

/s/_____
John S. Munn, M.D.
26

03/19/97 03/20/97 10:55 A

cc: 00511 John S. Munn, M.D.
01115 Todd White, M. ~ D

Form #227

676409

*** END OF REPORT ***

APPENDIX F

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN

No. 4:97-cv-116
[Filed November 6, 1999]

United States of America, Ex Rel.)
Jack Obeydean Swafford, a/k/a)
Dean J. Swafford,)
Plaintiffs,)
v.)
Borgess Medical Center, a nonprofit Michigan)
Corporation, Advanced Vascular Surgery, P.C.,)
a Michigan professional corporation, Krishna)
Jain, M.D., John Munn, M.D., Eugene Simoni,)
M.D., John T. Collins, Jr., M.D., and Randy)
Smejkal, M.D., P.C., a Michigan corporation,)
John T. Collins, Jr. M.D., Randy Smejkal,)
M.D., James McLaren, M.D., Healthcare)
Midwest General & Surgeons, a/k/a Healthcare)
Midwest, P.C., a Michigan corporation, Mark)
Tagett, M.D., Philip Borozan, M.D., Solomon K.)
Samuels, M.D., P.C., a Michigan corporation,)
Solomon K. Samuels, M.D., Padraic Carmody,)
M.D., Vascular Specialists, P.C., a Michigan)
corporation, Karim Abedel Abushmaies, M.D.,)
and M. Abidur Rahman, M.D., jointly and)
severally,)
Defendants.)

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AFFIDAVIT OF RICHARD SCHWARTZ. M,D.

STATE OF OHIO)
) SS
COUNTY OF)

I, RICHARD SCHWARTZ, being first duly sworn, depose and say that I have first-hand knowledge of the matters set forth herein, and am competent to testify as follows:

1. I am a Board Certified vascular surgeon licensed in the State of Ohio and attached hereto and included with this Affidavit is my curriculum vitae inclusive of my training, experience, licensure, etc. Included with my training and experience is the interpretation of venous ultrasound studies, and appropriate physician interpretation practices with respect thereto, i.e. review of hard copy print data (video) underlying the venous ultrasound study. I have been interpreting venous ultrasound studies and billing therefore, including Medicare/Medicaid patients, over the years, inclusive of 1991 to date. Further, I am familiar with the customs and practices of vascular surgeons who interpret and submit billing for all types of patients, including Medicare/Medicaid, patients for

venous ultrasound studies.

2. I have been provided with, and have reviewed various documents and materials such as the Affidavits of Dr. Phillip Borozan dated September 10, 1998 and September 28, 1999, the Affidavits of Dr. Krishna Jain dated August 10, 1998 and September 27, 1999, as well as various physician venous ultrasound reports and technicians/technologists "worksheets" from Borgess Hospital produced in the pending federal lawsuit (US Ex Rel Jack Swafford v Borgess Medical Center, et al).

3. Based upon my training and experience, I am familiar with and knowledgeable of the "professional" and "technical" component(s) Medicare/Medicaid billing requirements and procedures.

4. In my opinion, §2020 of the HCFA Medicare Carriers Manual is applicable to Defendant Physicians' "reading"/"interpretation" of venous ultrasound studies and billing and payment therefore relative to any Medicare/Medicaid patient.

5. In my opinion, any physician, including the Defendants physicians must personally furnish a "service" to a "beneficiary" (patient) which contributes directly to the diagnosis or treatment of the beneficiary, to properly bill and/or receive payment for the "service" with respect to any Medicare/Medicaid or Champus patient, including physician professional component billing for venous ultrasound study regardless of whether the study was "reported" by the vascular technician/technologist as negative for deep vein thrombosis.

6. In my opinion, the "physician services" must include the physician's visualization (video or photographs at a minimum) some aspect of the patient's condition in question, without the "interposition of a third person's judgment" including that of a technician or technologist. The vascular surgeons in this case billed and apparently received money from the federal government through the Medicare/Medicaid programs by (a) simply rewording or dictating the technician/technologists "worksheet", (b) assumed that the ultrasound was properly performed and (c) pursuant to the hospital/office protocol assumed that any aspect of the hospital/office protocol not addressed in the "worksheet" was normal when the physician dictated a report for the patient's hospital/office chart.

7. In my opinion, it is both the standard of care, and essential, that a qualified physician either personally perform the venous ultrasound study, or visualized/reviewed a videotape or (at minimum) hard copy print data (prints or photographs) thereof to determine whether the study was properly performed and provide an accurate interpretation of the study (not only whether a deep venous thrombosis is present but whether there is any other pathology or abnormality within or outside of the patient's vein(s).)

8. In my opinion, review of a videotape of a venous ultrasound study by a trained and qualified physician will reveal errors in the technician's performance of the technical aspects of the study, reveal whether the interpretation or report of the technician/technologist is accurate/complete and reveal whether there is any abnormality or pathology within or outside of the patient's vein(s) which may have been missed or not reported by the technician/technologist.

9. In my opinion, based on my training and experience, Defendant physicians' practice of dictating from or rewording the substance of the vascular technicians/technologists' "worksheet" with respect to a venous ultrasound study reported by the technician/technologist as negative for deep vein thrombosis, without reviewing a videotape of the study, assuming that the office or hospital "protocol" was followed by the technician and the physician further assuming that any or all of the five (5) factors (compressibility, augmentation, phasicity, spontaneity, compression) not addressed in the "worksheet" is/are normal is not an "interpretation" or a "reading" of the study by the physician, as those words are utilized in the physician component/billing 26 modifier.

10. In my opinion, and based upon my training and experience, the "result" (as the word is used in the "Professional Component" 26 Modifier) of the venous ultrasound is not the "worksheet" but, rather, the hard copy data underlying the study - the video tape of the venous ultrasound study.

Further affiant sayeth not.

/s/_____
RICHARD SCHWARTZ, M.D.

Subscribed and sworn to before me
this 6th day of November, 1999.

/s/_____
Josie Asmus-Cupp, Notary Public

CURRICULUM VITAE
RICHARD A. SCHWARTZ, M.D.

PRESENT ADDRESS:

Home: 205 Northridge
Perrysburg, Ohio 43551
419/874-1216

BIRTH DATE AND PLACE:

January 21, 1941
Cleveland, Ohio

FAMILY:

Wife:	Sandra		
Children:	Anne Christine	B/D	2/5/64
	Carrie Ruth	B/D	9/18/70
	Amanda Erin	B/D	9/10/81
	Karl Patrick	B/D	3/23/83

RELIGION:

Missouri Synod Lutheran

Education:

1. Lutheran High School West
Fairview Park, Ohio 1955-1959

2. The University of Toledo
College of Pharmacy

Toledo, Ohio
Degree B.S. in Pharmacy 1959-1963

3. Post Undergraduate Education
Baldwin Wallace College
Berea, Ohio - 1964

4. Post Graduate Education
University of California at Berkeley
Berkeley, California - Summer, 1965

MEDICAL EDUCATION

1. Medical College of Ohio at Toledo
South Detroit at Arlington
Toledo, Ohio
Degree: M.D.

POST GRADUATE EDUCATION:

1. Internship: Rotating
The Doctors Hospital (Now: Swedish Hospital & Medical Center)
909 University
Seattle, Washington - 1969-1970

2. Family Medicine Residency:

The Doctors Hospital (Now: Swedish Hospital & Medical Center)
909 University
Seattle, Washington -1972-1973

3. General Surgery Residency

The Jewish Hospital
Burnet Avenue
Cincinnati, Ohio -1972-1973
Chief: Henry J. Hemlich, M.D.

4. General Surgery Residency

Medical College of Ohio at Toledo
South Detroit at Arlington
Toledo, Ohio - 1973-1977
Chief Resident and Instructor in Surgery 1976-1977
Chief: William S. Blakemore, M.D.

5. Pediatric Surgery

Children's Orthopaedic Hospital
Sandpoint Way Northeast
Seattle, Washington -January-July 1975
Chief: Alexander H. Bill, M.D.

6. Vascular Surgery Fellowship

St. Vincent Hospital and Medical Center
2213 Cherry Street
Toledo, Ohio 43608
Chief: J. Robert Navarre, M.D.

WORK EXPERIENCE:

1. Assistant Chief Pharmacist
   Revco Drug Company
   Cleveland, Ohio -1963-1965

2. Chief Pharmacist
   Thrifty Drug Company
   Pittsburg, California -1964-1965

3. Family Medicine Practice
   Winslow Clinic
   Bainbridge Island, Washington -1971-1972

4. PRIVATE PRACTICE:

   a. Vascular and General Surgery
      235 South 4th Place
      Renton, Washington -1978-1979

   b. Vascular Surgery
      700 Mount Hope Avenue
      Bangor, Maine 04401 -1979-1975

5. Previous Positions:

   General and Vascular Surgery
   1162 S. Garl Street
   Burlington, WA 98233 -April 1985-December 1985

   General and Vascular Surgery
   251 Cohasset

Chico, CA 95926 (Locum Tenens)
916/895-1900

Vascular Surgery of Northwestern Ohio
3930 Sunforest Court
Toledo, OH 43623
419/475-9457

The Syldrum Medical Group
2955 Sylvania Avenue
Toledo, OH 43613
419/472-1124

GRANTS:

Ohio Division of American Cancer Society
Pancreatic Carcinoma - Microvasculature - $1,800.00

AWARDS:

Recipient of Marion Laboratories Award for Undergraduate paper titled, "Diagnosis and Treatment of Common Skiing Injuries as seen by the General Practitioner," $100.00.

ORGANIZATIONS:

Toledo Vascular Society
Pan Pacific Surgical Association
American Medical Association
Maine Vascular Society (Inactive)
Sigma Phi Epsilon, Kappa Psi. Atlas Club
Maine State Medical Association (Inactive)

Skagit-Island County Medical Association and Washington State Medical Association (Inactive)
Penobscot County Medical Association (Inactive)
International College of Surgeons, Vice President, U.S. Section 1983-1985
Bangor Medical Club (Inactive)
Pacific Northwest Vascular Society
Lucas County Academy of Medicine
Midwestern Vascular Society
Fellow American College of Surgeons
Fellow Surgical Society

MEDICAL LICENSES:

Ohio - M.D. 53441
Washington - M.D. 14781
Maine - M.D. 9818
National Board of Examiners Number - 156509
Board Certified: General Surgery 1979 - Recertified 1989
Board Certified: Vascular Surgery 1983 Certificate # 324 - November 18, 1983 Recertified 1996

POST GRADUATE MEETINGS:

1. American College of Surgeons
   Miami, Florida - October 1974

2. American College of Surgeons
   Dallas, Texas - October 1977

3. Ohio Medical Association
Display, Non-Invasive Venous Testing, May, 1976

4. American Cardiology Association
Display, Non-Invasive Venous Testing
Las Vegas, Nevada - March 1977

5. Ohio Cancer Society
Findlay, Ohio - February 1977

6. General Surgical Review
Cook County Graduate School of Medicine
Chicago, Illinois - December 1978

7. Vascular Surgery Symposium
San Francisco, California - February 1980

8. American College of Surgeons
Clinical Congress
Atlanta, Georgia - October 1980

9. American College of Surgeons
Vascular Surgery Section
Honolulu, Hawaii - February 1981

10. American College of Surgeons
Clinical Congress
Chicago, Illinois - October 1982

11. American College of Surgeons
Vascular Surgery Section
Acapulco, Mexico - February 1982

12. American College of Surgeons
Vascular Surgery Section
Fort Lauderdale, Florida - February 1982

13. Diasonics Ultrasound Course
San Jose, California - January 1983

14. New England Vascular Surgery Society
Mt. Washington, New Hampshire -
November 1982

15. International College of Surgeons
Trauma Symposium
Phoenix, Arizona - November 1984

16. International College of Surgeons
Problems in General Surgery
Orlando, Florida - March 1985

17. Pacific Northwest Vascular Society Meeting
Tacoma, Washington - November 1986

18. North Pacific Surgical Association
Tacoma, Washington - November 1986

19. Boston University School of Medicine
Laser Surgery Course
September 1987

20. Midwestern Vascular Society Meeting
Chicago, Illinois September 1987

21. Academy of Medicine
Winter Seminar IV 20 hours Cat. I
Barbados, West Indies - February 1988

22. A Comprehensive Review of Vascular Surgery
UCLA School of Medicine 32 Hours Cat. I
Santa Monica, California - October 1988

23. American Venous Forum
New Orleans, Louisiana - 16 Hours Cat. I
February 1989

24. Montefiore Medical Center
Review Course, New York - 50 Hours Cat. I
September 1989

25. Northwestern University
Techniques in Arterial Surgery -
16 Hours Cat. I
Deeember 7-9, 1989

26. American Venous Forum
San Diego, California - 16 Hours Cat. I
February 1990

27. Midwestern Vascular Surgical Society
September 14-15, 1990 - 12 Hours Cat. I
Toledo, Ohio

28. Swedish Hospital Radiology/Vascular
Surgery Conference
September 9-10, 1991 - 10 Hours Cat. I
Seattle, Washington

29. Wilderness Medical Society
Snowmass, Colorado
August, 1991 - 12 Hours

30. Pacific Northwest Vascular Society
Seattle, Washington
November, 1991 - 10 Hours

31. American College of Surgeons
Spring Meeting, March, 1992 - 10 Hours

32. Vascular Surgery Review
UCLA - Santa Monica, California
September, 1992 - 40 Hours

33. Ohio Academy of Family Physicians
Toledo, Ohio
November, 1993 - 10 Hours
(Faculty)

34. Emergency Medicine & Acute Care
Cancun, Mexico
January 1994 - 20 Hours

35. Toledo Surgical Society
Toledo, Ohio
March 17, 1994 - One Hour
(Faculty)

POSITIONS:

1. Chairman: Pharmacy and Therapeutics Committee,

Eastern Maine Medical Center,
Bangor, Maine - June 1981-
1983

2. Chairman: Utilization Review Committee
St. Joseph Hospital
Bangor, Maine - January 1981

3. Board of Directors Member
Main: Professional Review Organization (PRO) 1980-1985

4. Secretary - Treasurer
Vascular Associates
Bangor, Maine 1979-1985

5. Member Executive Committee
United First Methodist Church
Esses Street, Bangor, Maine
Pastor: Felix Miles - 1984

6. Chairman: Surgical Case Review Committee
St. Vincent Medical Center
Toledo, Ohio

7. Counselor: Lucas County Academy of Medicine 1989-1992

PAPERS AND PRESENTATIONS:

8-10-79 "Deep Vein Thrombosis", Eastern Maine Medical Center Residents, Bangor, Maine

12-4-79	"Blue Toe syndrome:, Mayo Regional Hospital Cover-Foxcroft, Maine
12-1-79	"Distal Tibial and Extra Anatomical Bypass Graft". State Wide Nurses Vascular Symposium, Bangor, Maine
1-8-80	"Vascular Surgery", EMMC School of Nursing, Bangor, Maine
3-6-80	"Vascular Surgery", James A. Taylor Osteopathic Hospital Physicians, Bangor, Maine
5-14-80	"Vascular Surgery", Clinical Care EMMC, Bangor, Maine
9-26-80	"Carotid Artery Disease", Mt. Desert Island Hospital, Bar Harbor, Maine
5-8-80	"Vascular Testing", Maine cost Memorial Hospital, Ellsworth, Maine
1-12-81	"Venous Disease", School of Nursing, EMMC, Bangor, Maine
1-27-81	"T.I.A./O.P.G.", Country Optometric Association, Bangor, Maine
5-5-81	"Abdominal Aortic Resection", CCU at EMMC, Bangor, Maine

9-29-81	"Surgical Care of the Patient with Venous Problems", EMMC, Bangor, Maine
10-3-81	Magnitude and Impact of Venous Disease on the Maine Economy." Director Venous Disease Symposium. Northern New England States
10-19-81	"An Evening in Vascular Surgery", Millinocket Regional Hospital, Millinocket, Maine
12-15-81	"Vascular Surgery", ICU, EMMC, Bangor, Maine
3-12-82	"Peripheral Vascular Disease", Waldo County Hospital, Belfast, Maine
4-24-82	"Popliteal Entrapment Syndrome", Maine Vascular Society, Waterville, Maine
11-17-82	"Sequential Distal Popliteal to Distal Tibial Bypass", Maine Vascular Society, Waterville, Maine
1-14-83	"Surgery of the Occluded Carotit Artery", ACS Tristate Meeting, North Conway, New Hampshire
4-13-83	"Management of the Burn and Penetrating Vascular Trauma", Maine Emergency Medical Society, Bangor, Maine

5/27-29/83	"Director, EMMC Arterial Disease Symposium, New Brunswick, Canada. Maine, New Hampshire, Vermont
1986	February, April, June, August, October, December - "Circulatory Shock" lecture to Third Year Medical College of Ohio Students, St. Vincent Medical Center
6-19-87	"Uncommon Presentations of Temporal Arteritis", Fremont Memorial Hospital, Fremont, Ohio
7-87	"Diagnosis and Prevention of Arteriosclerosis". St. Vincent "Golden Age" Education Program
9-87	Nursing Vascular Education Symposiums. Fremont Memorial Hospital, Fremont, Ohio
11-87	"Neurophysiology of Stroke", Vascular Fellowship Program, St. Vincent Medical Center
1988	February, April, June, August, October, December, "Circulatory Shock" Lecture to Third Year Medical College of Ohio students, St. Vincent Medical Center
2-88	"Laser Assisted Balloon Angioplasty", Academy of Medicine, Winter Seminar IV. Barbados, West Indies

4-88	Trauma Symposium, "Indications for Greenfield Filter", St. Vincent Medical Center
8-88	"Lower Limb Revascularization", Saphenous Vein Reversed In-situ Sequential Bypass", Vascular Fellowship Program. St. Vincent Medical Center
8-88	"The Vascular Surgeon and Laser Assisted Balloon Angioplasty", Fremont Memorial Hospital
9-88	"Indications for Greenfield Filter", St. Vincent Orthopaedic Symposium
10-88	"The Vascular Surgeon and Laser Assisted Balloon Angioplasty", Kiwanis Club, Toledo, Ohio
11-88	"Lower Limb Reconstructions. Dardik Grafts and Fistulas. Use of Synthetic Grafts". Vascular Fellowship. St. Vincent Medical Center
1-89	Case Review, Vascular Fellowship Program, St. Vincent Medical Center
3-89	"Renal Access", Vascular Fellowship Program, St. Vincent Medical Center
4-89	Angiography Review, Vascular Fellowship Program, St. Vincent Medical Center

8-89	"Cold Weather, Cocaine, and Arteries", Vascular Fellowship Program, St. Vincent Medical Center
9-89	"Greenfield Filter", Fremont Memorial Hospital Staff
10-89	"Greenfield Filter", Addison Hospital
12-89	"Cocaine, Cigarettes, Cold Weather and Your Arteries", Williams County Hospital
2-90	"Greenfield Filter Indications in 2nd Patients and Follow-up", San Diego, California
11-93	"Diagnosis and Prevention of Deep Venous Thrombosis and Pulmonary Emboli for the Family Physician", Ohio Academy of Family Physicians, Toledo, Ohio
2-94	"Indications for Greenfield Filter", Sullivan, Martinez, Clark, Lemon, and Schwartz. S.G.O. 2-94
3-94	"What is a Recycling Physician and What is Their Impact on Family Medicine?" (Submitted for publications to *American Family Physician*.)
3-94	"The Future of Surgery - How to Recycle". Toledo Surgical Society. Toledo, Ohio

No. 01-1399

Supreme Court, U.S.
FILED

APR 18 2002

OFFICE OF THE CLERK

In The

Supreme Court of the United States

UNITED STATES *ex rel.* SWAFFORD,

Petitioner,

v.

BORGESS MEDICAL CENTER, ET AL.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Sixth Circuit

BRIEF IN OPPOSITION FOR RESPONDENTS ADVANCED VASCULAR SURGERY, P.C.; KRISHNA JAIN, M.D.; JOHN MUNN, M.D.; EUGENE SIMONI, M.D.; JOHN T. COLLINS, JR., M.D., AND RANDY SMEJKAL, M.D., P.C.; JOHN T. COLLINS, JR., M.D.; RANDY SMEJKAL, M.D.; JAMES MCLAREN, M.D.; SOLOMON K. SAMUELS, M.D.; PADRAIC CARMODY, M.D.; KARIM ABEDEL ABUSHMAIES, M.D.; AND M. ABIDUR RAHMAN, M.D.

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OR CALL COLLECT (402) 342-2831

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, corporate Respondents Advanced Vascular Surgery, P.C., Randy Smejkal, M.D., P.C., Solomon K. Samuels, M.D., P.C., and Vascular Specialists, P.C., make the following disclosures:

1. Each of the foregoing corporate Respondents is a privately held corporation;

2. There is no parent or publicly held company owning 10% or more of stock in any of the foregoing corporate Respondents.

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United States ex rel. Hagood v. Sonoma County Water Agency, 81 F.3d 1465 (9th Cir. 1996) 4, 5, 6

United States ex rel. Lamers v. City of Green Bay, 168 F.3d 1013 (7th Cir. 1999) 5, 6

United States ex rel. Roby v. The Boeing Company, 100 F.Supp.2d 619 (S.D. Ohio 2000) 4

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31 U.S.C. § 3730(b)(2) 1

I. COUNTER-STATEMENT OF THE CASE

Petitioner brought this action in the United States District Court for the Western District of Michigan in which he claimed that Respondents violated the False Claims Act, 31 U.S.C. § 3729, *et seq.* (the "Act"), by falsely charging the government for medical services which they allegedly did not perform adequately.[1] At issue were certain laboratory tests performed by vascular technicians, who prepared written reports setting forth the test results for each patient. It is undisputed that *for every patient* the Respondent-physicians reviewed the test results and prepared a written report setting forth their medical conclusions and findings, thereafter billing the federal government for an "*interpretation or reading of the **results*** of the test performed."[2] The gist of Petitioner's claim was that the information reviewed by the Respondent-physicians was somehow insufficient under the applicable "standard of care" to allow the physicians to make a medically adequate finding, and, in turn, submit a claim for those services.

---

[1] Petitioner proceeded under the Act's *qui tam* provisions after the government declined to join the suit as a party. 31 U.S.C. § 3730(b)(2).

[2] The tests at issue consisted of two "components" under applicable billing guidelines. The technicians performed the "technical component" (defined as the "actual performance of the test"), following which the physicians performed the "professional component" (defined as the "interpretation or reading of the results of the test performed"). Consistent with these guidelines, after reviewing the test results and preparing their interpretive report, the physicians billed only for performing the "professional component."

Following discovery concerning the services provided by the physicians,[3] the District Court granted Respondents' motion for summary judgment because it was undisputed that the Respondent-physicians *actually provided* a service for *every* patient, because no applicable law or regulation required the service to be performed in the manner argued by Petitioner, and because claims under the Act cannot be based on issues of professional judgment or scientific methodology. Consequently, there was no basis on which it could reasonably be argued or found that the underlying claims were either "false" or presented with the requisite "scienter" to impose liability under the Act. The Sixth Circuit subsequently affirmed (by *per curiam* opinion) the District Court's grant of summary judgment.

---

[3] Petitioner's "Statement of Facts" on appeal to the Sixth Circuit argued that the discovery process ordered by the District Court (reflecting a discovery order agreed to by the parties) somehow limited his argument on the issue of scienter. But neither there, nor here, does Petitioner identify any specific, material fact relied upon in the District Court's grant of summary judgment which remained unexplored or unsupported. In fact, Petitioner simply *never raised* this issue before the trial court, nor did he raise a claim that his ability to argue the scienter issue was somehow impaired because of inadequate discovery. Indeed, the Petitioner *failed to pursue* the full extent of the discovery agreed to by the parties and authorized by the District Court (e.g., by taking only three physician depositions even though six physician depositions were authorized, etc.). This issue was not decided below and should not be decided here. *National Collegiate Athletic Assn. v. Smith*, 525 U.S. 459, 470, 119 S.Ct. 924, 930, 142 L.Ed.2d 929 (1999).

II. REASONS FOR DENYING THE WRIT

Although the Petition argues various issues, the Petitioner's claim ultimately focuses on one basic question: should the Act be judicially reformed to reduce the statutorily mandated standard for imposing liability? The Act expressly requires a showing that the submitted claim was both "false," and presented with "actual knowledge, deliberate ignorance or reckless disregard of its falsity." 31 U.S.C. § 3729(a) and (b). Petitioner argues that the Act's standard of liability should be lowered to include claims based on a medical "standard of care," notwithstanding the plain language of the Act which expressly negates that proposition. As discussed below, the legal principles relied on by the District Court and Sixth Circuit are well-established and consistent with the requirements of the Act, and Petitioner's arguments are simply a quarrel with the application of the underlying facts to properly stated rules of law.

The District Court and Court of Appeals correctly applied both the provisions of the Act and well-established precedent under the Act. Further review is therefore unwarranted.

A. The District Court Properly Applied Both Statutory Provisions And Well-Established Case Law To Find That No False Claim Had Been Submitted. There Is No Circuit Conflict To Support The Court's Discretionary Exercise Of Certiorari Jurisdiction.

The District Court properly determined that Petitioner failed to present a genuine issue of material fact as to whether Respondents had submitted claims that were

false. "Falsity" for FCA purposes requires proof of an objective falsehood. *United States ex rel. Roby v. The Boeing Company,* 100 F.Supp.2d 619, 625 (S.D. Ohio 2000), *citing, United States ex rel. Hagood v. Sonoma County Water Agency,* 81 F.3d 1465, 1477-1478 (9th Cir. 1996). No evidence of intrinsic falsity, i.e., evidence that reimbursement was fraudulently sought for services not actually provided, was found. This conclusion was particularly compelling given Petitioner's inability to dispute that *for every patient,* the Respondent-physicians *actually* reviewed the test results reported by the technicians (the "technical component" of the test), following which the physicians prepared a written report reflecting their medical interpretation and judgment (the "professional component" of the test) regarding the presence of a deep vein thrombosis (DVT) or other vascular abnormality in the patient so the delivery of health services could be tailored accordingly. Simply put, the undisputed evidence demonstrated that the Respondent-physicians *actually* performed the service for which they submitted a claim.

Further, Petitioner produced no evidence of any extrinsic falsity that could give rise to liability under the Act, i.e., the failure to comply with some statute or regulation that was a material condition to receiving payment from the government. No specific laws or regulations have been promulgated to govern the submission of reimbursement claims for venous ultrasounds. Likewise, the District Court properly declined to judge the truth or falsity of Respondents' claims in light of guidelines *not applicable* to the physicians or by reference to allegedly analogous protocols published for other procedures; the District Court correctly found that these "standards"

were inapplicable to the claims submitted by Respondents (and the underlying medical studies), and lacked the binding effect of law. *National Medical Enterprises v. Bowen*, 851 F.2d 291, 293 (9th Cir. 1988). *See also, United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) (noting that the Act is not a suitable vehicle for policing technical compliance with administrative regulations).

Ultimately, in arguing liability under the Act based on the allegedly applicable medical "standard of care," the Petitioner only raises a debate over issues of professional judgment and scientific methodology. It is well-established that the Act is not a proper forum for such debate. *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730 (7th Cir. 1999); *Hagood v. Sonoma County Water Agency, supra*, at 1478 (9th Cir. 1996).

The District Court and Sixth Circuit correctly ruled that Petitioner failed to produce evidence that the claims submitted by the Respondent-physicians were false under any factual or legal theory. The Petition in this case is nothing more than an attempt to reargue this factual finding, and should be denied.

B. The Court Correctly Found That The Respondent-Physicians' Practice With Regard To Interpretation Of Venous Ultrasound Studies Did Not Amount To Deliberate Ignorance Of, Or Reckless Disregard For, Applicable Guidelines For Submission Of Claims.

Nor did Petitioner come forward with evidence of scienter, i.e., evidence that the claims were presented

with "actual knowledge, deliberate ignorance or reckless disregard of its falsity." 31 U.S.C. § 3729(b). The District Court and Sixth Circuit also correctly granted summary judgment on this issue.

Both the express provisions of the Act and cases decided under it make clear that the "requisite intent is the knowing presentation of what is known to be false." *Hindo v. University of Health Sciences*, 65 F.3d 608, 613 (7th Cir. 1995), *citing, Hagood, supra; Wang v. FMC Corp.*, 975 F.2d 1412, 1420 (9th Cir. 1992) ("In short, the claim must be a lie"). Disputes as to the interpretation of regulations do not give rise to liability under the Act. *Hagood, supra,* at 1477. *See, United States ex rel. Lamers v. City of Green Bay, supra,* at 1019 (technical violations of a federal regulation on which a claim is based do not make the claim "false"); *Luckey v. Baxter Healthcare Corp., supra.*

Given the undisputed evidence that the Respondents *actually provided* a service *for every patient,* coupled with the lack of any applicable billing guidelines and evidence of ongoing efforts by the physicians to ensure compliance with any regulatory mandates, the District Court and Sixth Circuit properly found that Petitioner failed to produce evidence of the requisite scienter. On this issue as well, Petitioner's argument presents nothing more than an attempt to reargue the District Court's factual finding that the requisite scienter is lacking. The Petition should be denied.

C. The "Questions Presented" Do Not Warrant This Court's Exercise Of Discretionary Certiorari Jurisdiction.

The Petition also fails to set forth any compelling reasons why it should be granted. The principles of law relied on by the District Court and Sixth Circuit are consistent with the Act, and reflect well-established principles on which there is no conflict among the circuits or state courts of last resort. Likewise, Petitioner's characterization of his case as presenting "questions of national importance" is flawed, particularly since asserted error consisting in "erroneous factual findings or the misapplication of a properly stated rule of law" are not sufficiently compelling to invoke certiorari jurisdiction under Supreme Court Rule 10. Simply put, no question of national importance is presented, and there is no compelling basis for review. *National Collegiate Athletic Assn. v. Smith*, 525 U.S. 459, 470, 119 S.Ct. 924, 930, 142 L.Ed.2d 929 (1999); *Holly Farms Corp. v. National Labor Relations Board*, 517 U.S. 392, 116 S.Ct. 1396, 134 L.Ed.2d 593 (1996).

The District Court and Sixth Circuit Court's rulings fail to implicate any issue warranting further review of this matter. Respondents respectfully request this Honorable Court to deny the Petition for Writ of Certiorari.

III. CONCLUSION

For the foregoing reasons, the Petition for Writ of Certiorari should be denied.

Respectfully submitted,

JOHN W. ALLEN
Counsel of Record
JEFFREY D. SMITH
JENNIFER J. STOCKER
VARNUM, RIDDERING, SCHMIDT & HOWLETT LLP
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No. 01-1399

Supreme Court, U.S.
FILED
APR 18 2002
OFFICE OF THE CLERK

In The

Supreme Court of the United States

UNITED STATES OF AMERICA, EX REL. JACK OBEYDEAN SWAFFORD, also known as Dean J. Swafford,

Petitioner,

v.

BORGESS MEDICAL CENTER, a nonprofit Michigan corporation; ADVANCED VASCULAR SURGERY, P.C., a Michigan professional corporation; JAIN KRISHNA, M.D.; JOHN MUNN, M.D.; EUGENE SIMONI, M.D.; JOHN T. COLLINS, JR., M.D. AND RANDY SMEJKAL, M.D., P.C., a Michigan corporation; JOHN T. COLLINS, JR., M.D.; RANDY SMEJKAL, M.D.; JAMES MCLAREN, M.D.; HEALTHCARE MIDWEST GENERAL & SURGEONS, also known as Healthcare Midwest, P.C., a Michigan corporation; MARK TAGETT, M.D.; PHILIP BOROZAN, M.D.; SOLOMON K. SAMUELS, M.D., P.C., a Michigan corporation; SOLOMON K. SAMUELS; PADRAIC CARMODY, M.D.; VASCULAR SPECIALISTS, P.C.; a Michigan corporation; KARIM ABEDEL ABUSHMAIES, M.D.; M. ABIDUR RAHMAN, M.D., jointly and severally,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Sixth Circuit

OPPOSITION BRIEF OF RESPONDENTS HEALTHCARE MIDWEST, P.C., MARK TAGETT, M.D., AND PHILIP BOROZAN, M.D.

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QUESTION PRESENTED

Whether a writ of certiorari is necessary to review the decision of the United States Court of Appeals for the Sixth Circuit to affirm the United States District Court for the Western District of Michigan's opinion granting the Respondents summary judgment when:

(1) The Petitioner conceded that there was no regulation or law requiring the Respondents to perform venous ultrasound studies in the manner advocated by the Petitioner; and

(2) The other circuits addressing the issue agree that in the absence of a controlling regulation or law, a dispute over how best to perform a test or study is not actionable.

PARTIES TO THE PROCEEDING

In addition to the parties identified by the Petitioner, the United States of America is an interested party in this case. The Petitioner brought his False Claims Act claims against the Respondents as a private citizen or "relator." The United States, through the Department of Justice, had an opportunity to intervene in this action. In this case, the United States declined to intervene. Moreover, the United States – acting as Amicus Curiae – filed a brief supporting affirmation of the District Court's decision.

CORPORATE DISCLOSURE STATEMENT

Respondents Philip Borozan, M.D. and Mark Tagett, M.D. are individuals who are not required to submit a corporate disclosure statement. Respondent Healthcare Midwest, P.C. is not the subsidiary or affiliate of a publicly-owned corporation. Nor is there a publicly-owned corporation not a party to the appeal that has a financial interest in the outcome.

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COUNTER-STATEMENT OF THE CASE

This Petition is brought by Jack Obeydean Swafford ("Swafford"), who asserts that Respondents Philip Borozan, M.D., Mark Tagett, M.D., and Healthcare Midwest P.C. (the "Physicians") have committed fraud under the False Claims Act ("FCA"). In his Petition, Swafford argues that the United States District Court for the Western District of Michigan and the United States Court of Appeals for the Sixth Circuit improperly granted and affirmed summary judgment in favor of the Physicians.

At every stage of this case, Swafford has argued that the Physicians have allegedly committed fraud because they have not read or interpreted venous ultrasound studies reported as negative for deep vein thrombosis.[1]

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[1] A venous ultrasound (or doppler) study consists of two components. (Pet. App. at 39a.) The first is the technical component, during which vascular technicians or registered vascular technologists objectively test four characteristics – spontaneity, augmentation, phasicity, compressibility – of a patient's veins. (*Id.* at 40a.) These tests are objective because the results are binary: i.e., a vein is compressible or not. There is no intermediate result. (*Id.* at 41a.) The technicians report the test results on a worksheet. (*Id.* at 40a.)

The second part of the venous study is the professional component, in which trained physicians read or interpret the findings reported on the technicians' worksheets. (*Id.* at 40a-41a.) The physicians review the test data and integrate that information with any relevant information contained in the patient's file, and any other available or known relevant information in order to make a conclusion about the study (i.e., whether the test is negative or positive for deep vein thrombosis, needs to be repeated, or is negative for deep vein thrombosis but reveals other incidental abnormalities). (*Id.* at 44a-45a.)

Swafford claims that in order to perform a reimbursable "service," (i.e., an "interpretation" or "reading" of the results of a venous ultrasound study), the physicians must have actually viewed the videotapes or photographs (instead of the paper worksheets) produced by the technicians performing the study. According to Swafford, unless the Physicians viewed the videotapes, any billing to the federal government for physician services in connection with negative venous studies is a false claim.

No applicable law or regulation, however, requires the physicians to view a videotape or photograph in connection with their interpretation or reading of the venous studies. Thus, whether the physicians must review a videotape or photograph is really a question of whether the appropriate standard of care has been provided to the patient. As both the District Court and the Court of Appeals ultimately concluded, disputes about whether the provided services fall short of the standard of care are not actionable.

Believing Swafford's claims to be meritless, the Physicians filed a motion to dismiss Swafford's FCA action in September 1999. After denying the motion to dismiss, the District Court ordered limited discovery to determine whether the Physicians provided a service of some value, or did nothing at all before they billed for the reading of the studies. In other words, the District Court, in its discretion, decided that the Petitioner would first be required to find evidence of "falsity" before proceeding with additional discovery.

Upon completion of this limited phase of discovery, the Physicians moved for summary judgment. After

reviewing all the evidence and hearing from both parties, the District Court concluded that Swafford failed to show that there was a genuine issue of material fact with respect to his claims:

> In conclusion, plaintiff's disagreement with the qualitative nature and degree of review necessary for defendant physicians to claim to "interpret" the technical component of a venous ultrasound study and then bill the government for the professional component fails to amount to either a false claim or knowingly false claim under the FCA. . . . Moreover, even were plaintiff to succeed in demonstrating defendants submitted false claims because they did not review the underlying hard copy data from the studies, the record fails to establish that defendants acted either in deliberate indifference or reckless disregard of the truth of the claims.

(February 18, 2000 Opinion ("Op.") at 24 (Pet. App. at 23a-24a).) The District Court particularly noted that Swafford "does not deny . . . that defendant physicians reviewed the materials. . . . " (*Id.* (Pet. App. at 19a).) Concluding that the Physicians did perform a service of value, the District Court granted summary judgment in the Physicians' favor, dismissing Swafford's claims.

Swafford then appealed this decision to the Court of Appeals, which issued a pithy opinion on December 12, 2001 affirming the District Court. (Pet. App. at 27a-29a.) Reviewing the District Court's grant of summary judgment de novo, the Court of Appeals found no error with the District Court's conclusion that Swafford failed to present actionable FCA claims.

REASONS FOR DENYING THE WRIT

Two courts have already examined the issues raised in Swafford's complaint. Both have concluded that summary judgment in favor of the Physicians is appropriate. Despite this, Swafford now requests a writ of certiorari review even though he has failed to show a compelling reason warranting this Court's involvement. Although Swafford offers a number of bases to justify this Court's review (none of which are clearly articulated), his primary arguments appear to be (1) the lower courts failed to consider certain guidelines and the standard of care when it concluded that the Physicians did not make false claims and (2) there were genuine issues of material facts that precluded summary judgment. Swafford is incorrect in his assessment of the lower courts' "errors."

As both lower courts properly concluded, there is no law or regulation requiring the Physicians to review the videotapes of venous ultrasound studies. Nor does Swafford's suggestion that the Physicians have violated the appropriate standard of care create an important question for the Court. The nation's federal courts have repeatedly held that when parties, who agree that a service has been provided, only question whether the service satisfied a standard of care, no FCA claim will lie. *See, e.g., Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 731-33 (7th Cir. 1999) (affirming summary judgment).

In short, the lower courts were correct to grant the Physicians' motion for summary judgment and there is no reason why this decision should be reversed or even reviewed by the Court. Thus, the Respondents respectfully request that the Court deny the Petition.

I. THE LOWER COURTS' DECISIONS ARE CONSISTENT WITH THE DEVELOPED RULE OF LAW THROUGHOUT THE CIRCUITS AND THUS FAIL TO RAISE AN IMPORTANT QUESTION FOR THIS COURT.

Swafford's Petition so confuses and conflates the issues in this case, it is difficult to ascertain what exactly is the important question necessitating this Court's review. Sup. Ct. R. 10(a), (c). Yet, it appears that – among other issues – Swafford disputes the lower courts' conclusion that there was no applicable law or regulation governing the submission of claims for the venous ultrasound studies. (Pet. App. at 12-24.) Swafford apparently forgets that he already conceded this issue in the District Court:

> THE COURT: Mr. Gagleard, this is not that hard a question to answer, and I'm going to try it one last time, and if you won't answer it, then I'm going to assume that there is nothing in the regulation that's provided to the physicians that makes such a requirement. You quote extensively from the Carrier Manual. You quote from cases. I don't see anything that you quote from that Provider Manual that says that they had to look at the still photos or look at the video. Now, I understand you are making arguments about this means that, but I don't see any reference to a portion of the Provider Manual that says that they were required to do what you were requiring [them] to do. Am I right about that or am I wrong?
>
> MR. GAGLEARD: I believe you are accurate. There is nothing that says that the radiologist –

> strike that. *There's nothing that says that you have to look at the video or the photos.*

(November 29, 1999 Summary Judgment Hearing Transcript ("Tr.") at 29-30 (Resp. Br. App. 10-11.) (emphasis added).)

If there is no regulation or guidance requiring the Physicians to do what Swafford claims they should have done, there is no false claim under the FCA. Neighboring circuits concur. *See Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 731-33 (7th Cir. 1999) (affirming summary judgment dismissing FCA claims since none of the federal regulations required the defendant to test blood plasma in the method or manner the plaintiff thought the blood should be tested).

The circuit courts have also held that when parties disagree over the *nature* of the performance of a particular procedure or test (for which a claim for reimbursement is being made), there is no basis for an FCA action.[2] *Id.* at 733 ("All this record reveals is a dispute about whether Baxter's testing protocols could be improved. An affirmative answer to that question would not suggest that Baxter's representations to the United States in the years past were false or fraudulent."); *Mikes v. Straus*, 274 F.3d 687, 702 (2d Cir. 2001) ("[D]efendants did not submit impliedly false claims by requesting reimbursement for

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[2] This Court has not addressed the legal issues presented in this case.

spirometry tests that allegedly were not performed according to the recognized standards of health care.").[3]

These circuits have specifically indicated that "ineffective testing" is not the same as "no testing." *See, e.g., Luckey*, 183 F.3d at 732. Thus, disputes relating to the level of care provided by the provider are not actionable under the FCA. If a defendant physician bills for a test or service which she provides, but in doing so fails to provide the highest level of care advocated by the plaintiff, this does not give rise to a false claim. *See, e.g., Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1998) (" . . . [T]he common failings of engineers and other scientists are not culpable under the Act."). Certainly, this makes sense since disputes over the appropriate standard of care concern questions of scientific judgment. If the courts were to allow FCA claims predicated on an inappropriate level of care, then every medical malpractice claim would be subject to FCA liability and the federal government would find itself in the unenviable position of prosecuting these types of claims. *See Mikes*, 274 F.3d at 700.

The record in this case reveals that Swafford does not dispute that the Physicians provided some service: i.e., reading and reviewing the worksheets prepared by the technicians who conducted the venous ultrasound test. (Tr. at 25 (Resp. Br. App. 6).) Thus, Swafford's argument is not whether the Physicians provided a service but rather, whether the Physicians provided "enough" of a

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[3] *See also Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1998); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 889 (5th Cir. 1997).

service by only reading and interpreting the worksheets, and not the videotapes of the tests.[4] (Tr. at 47 (Resp. Br. App. 27).) Simply put, Swafford argued that the Physicians did not satisfy the purported standard of care for venous ultrasound studies. Relying on *Luckey*, *Mikes*, and other cases, the District Court concluded as a matter of law that Swafford's claims that the Physicians did not do more in reviewing the venous ultrasound studies were not actionable:

> The Court finds the reasoning of these authorities quite persuasive, and concludes plaintiff cannot demonstrate a genuine issue of material fact with respect to false claims under the FCA, even if he can demonstrate defendants' practice failed to conform to the standard of care applicable to the interpretation of venous ultrasounds.

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[4] Thus, this case is different from *United States v. NHC Healthcare Corp.*, 115 F.Supp.2d 1149 (W.D. Mo. 2000). (Petition at 21-23.) In *NHC*, the plaintiff's claims were brought under the theory that the services provided by the defendant were so severely deficient that essentially no service was provided. The district court noted that "[t]he billing dispute at issue here is not *how* the Defendant turned, bathed, administered drugs to, and fed the two residents in question, but whether the Defendant did these things *at all*." *Id.* at 1155 (emphasis added). As the *NHC* court acknowledged, these circumstances were markedly different from those in *Mikes*, in which it was evident the physicians had provided a service of some medical value. In this case (as in *Mikes*), it is uncontroverted that the Physicians provided a service of value to their patients. (Pet. App. 19a, 38a-47a; Tr. at 25 (Resp. App. Br. 6).)

(Op. at 18 (Pet. App. at 18a-19a).) This finding was affirmed by the Sixth Circuit. (December 12, 2001 Opinion ¶ 1 (Pet. App. at 28a).)

Apart from the inapposite *United States v. NHC Healthcare Corp.*, 115 F. Supp.2d 1149 (W.D. Mo. 2000), discussed *supra* at n.4, Swafford has not cited one case to support his belief that the issues raised in this lawsuit present an important matter in which the various circuits are in conflict. If anything, it appears that the courts addressing this issue (including the district court in *NHC*) would agree with the lower courts' conclusion that Swafford's claims are not viable. Swafford's claims only challenge the Physicians' scientific judgment as to the appropriate level of care. Such disputes do not support an FCA action as a matter of law. This Court should deny the request for writ.

II. THE DECISION GRANTING SUMMARY JUDGMENT IS NOT UNUSUAL GIVEN THE ABSENCE OF CONTROLLING LAW AND THE UNCONTROVERTED EVIDENCE THAT THE PHYSICIANS PROVIDE A SERVICE OF VALUE.

Swafford argues that summary judgment was inappropriate because there were numerous and genuine issues of material facts concerning (1) the law and regulations governing the performance of venous ultrasound studies and (2) the Physicians' intent. However, Swafford never argues or explains why the summary judgment decision was so far departed from the usual course of judicial proceedings that further review is warranted.

Sup. Ct. R. 10(a). This is probably because such an argument would be specious, at best.

Swafford first contends that there are genuine issues of material facts such as whether the Physicians submitted false claims in light of the standard of care, various manuals and regulations. (Pet. at 14-17.) The District Court concluded that *all* of the extraneous materials offered by Swafford are not applicable:

> Given the lack of specific billing regulations concerning venous ultrasounds, the Court is not persuaded by plaintiff's arguments. As a matter of law, the Court concludes plaintiff's position on this issue is insufficient to establish a genuine issue of material fact. Plaintiff concedes HCFA [the Health Care Financing Administration] has not promulgated specific regulations relating to the submission of reimbursement claims for venous ultrasounds. . . . Plaintiff has neither established that compliance with these [other] standards is a prerequisite for reimbursement by Medicare for venous ultrasounds, nor adduced any facts to support an inference that the physicians knew or believed these regulations to be applicable to their submissions.

(Op. at 10-11 (Pet. App. at 11a-12a).) Swafford's Petition fails to explain why the District Court's holding is incorrect. Swafford does not provide any persuasive authority arguing that the various manuals and regulations cited in the Petition are applicable to venous ultrasound studies. Rather, as noted earlier (*supra*, Section I), Swafford admitted that Medicare has not specifically promulgated regulations governing a physician's interpretation of venous

ultrasound studies.[5] When Swafford himself concedes that there are no controlling regulations, a decision granting summary judgment is neither unusual nor suspect.

Swafford next argues that the District Court erred when it concluded that there was no genuine issue of material fact regarding the Physicians' intent. Swafford complains that the District Court applied the wrong standard when it found there was no evidence of intent. Unfortunately for Swafford, he never challenged the scienter standard used by the District Court on appeal; thus, the issue is now waived. *See Bickel v. Korean Air Lines Co., Ltd.*, 96 F.3d 151, 153-54 (6th Cir. 1996) (concluding that appellant waived issue when it failed to raise the issue in its opening brief).

Swafford's contention is also just plain wrong. The District Court specifically articulates in Section IV of its Opinion the very standard Swafford argues for in this case. (February 18, 2000 Opinion at 21 (Pet. App. at 21a) ("To succeed under the FCA, a relator need not demonstrate specific intent to defraud the government."). Using the correct standard, the District Court concluded that the Physicians lacked the requisite level of intent because they believe they are providing a service when they review the technicians' worksheets (Pet. App. 38a-47a), Swafford has already admitted that the Physicians do review and read the worksheets (Tr. at 25 (Resp. Br. App. 6)), and there is no regulation or law requiring the Physicians to do more than this. Swafford fails to provide a

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[5] *See also* Op. at 9 (Pet. App. at 10a) (*citing* Pl. Orig. Br. at 1, n.4, Dkt. No. 6).

persuasive or compelling reason why this decision of the District Court (and the Sixth Circuit) is so extraordinary that it should be reviewed by this Court. As such, the request for writ must be denied.

CONCLUSION

For the reasons stated above, Respondents Healthcare Midwest, P.C., Mark Tagett, M.D., and Philip Borozan, M.D. respectfully request that this Honorable Court deny the Petition for Writ of Certiorari.

Respectfully submitted,

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Dated: April 18, 2002

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA, EX REL. JACK OBEYDEAN SWAFFORD, a/k/a DEAN J. SWAFFORD,

Plaintiffs,

vs. No. 4:97-CV-116

BORGESS MEDICAL CENTER, a nonprofit Michigan corporation, ADVANCED VASCULAR SURGERY, P.C., a Michigan professional corporation, KRISHNA JAIN, M.D., JOHN MUNN, M.D., EUGENE SIMONI, M.D., JOHN T. COLLINS, JR. M.D., and RANDY SMEJKAL, M.D., P.C., a Michigan corporation, JOHN T. COLLINS, JR., M.D., RANDY SMEJKAL, M.D., JAMES McLAREN, M.D., HEALTHCARE MIDWEST GENERAL & VASCULAR SURGEONS, a/k/a HEALTHCARE MIDWEST, P.C., a Michigan corporation, MARK TAGETT, M.D., PHILIP BOROZAN, M.D., SOLOMON K. SAMUELS, M.D., P.C., a Michigan corporation, SOLOMON K. SAMUELS, M.D., PADRAIC CARMODY M.D., KARIM ABEDEL ABUSHMAIES, M.D., and M. ABIDUR RAHMAN, M.D., jointly and severally,

Defendants.
_____/

(Filed Jun. 19, 2000)

DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT
BEFORE THE HONORABLE DAVID W. McKEAGUE
UNITED STATES DISTRICT JUDGE
Lansing, Michigan, November 29, 1999, at about 1:55 P.M.

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* * *

[21] Mr. Gagleard.

MR. GAGLEARD: Thank you, Your Honor.

THE COURT: While it's fresh in my mind, let's start with those same questions.

MR. GAGLEARD: Okay.

THE COURT: Do you have any disagreement with what Mr. Smith and Mr. Lloyd have said?

MR. GAGLEARD: Some. I believe that you may have a partial obstruction and you may have one or more of the five factors be negative or be positive and yet have an acute partial blood clot – I'm sorry – a partial obstruction or [22] you may have a total obstruction. This is – this is not one of the processes whereby you would present and there is either a blood clot or there is no blood clot. As a matter of fact, you can have a complete obstruction, you can have a partial obstruction. You can have an acute blood clot or you can have a chronic blood clot. Chronic blood clot is one that's been around for a while, doesn't necessarily require immediate treatment, and is not necessarily a medical emergency.

THE COURT: Well, regardless of whether the positive finding is DVT or something less than that, if there is such a thing –

MR. GAGLEARD: Yes, sir.

THE COURT: – is the procedure that first Mr. Smith and then Mr. French agreed to what you understand happens here? These doctors are asked to come in and read these tests for any number of reasons and they go and they find a work sheet, and maybe it's accompanied by other things and maybe it isn't, and they don't know in advance whether it's going to be positive, negative, or negative with an abnormality.

MR. GAGLEARD: I'd agree with that.

THE COURT: Now, you are contending in this case that they can't bill for a report that they dictate based upon a work sheet that is negative for DVT, correct?

MR. GAGLEARD: That's true.

THE COURT: There was some question in, I think, Mr. [23] French's mind as to whether you were also contending that they couldn't bill for a report that they dictate that is negative with an abnormality.

MR. GAGLEARD: Well, it depends which abnormality. There are a few that haven't gone through many of these, hundreds of these, thousands of these, more days that I care to think about in Borgess's storage house –

THE COURT: So there's some negative with abnormalities they can bill for and other negative with abnormalities they can't? Is that it in a nutshell?

MR. GAGLEARD: The other abnormalities deal with reflux, for example, which means the blood's going in the wrong direction, or it can mean a Baker cyst, which –

THE COURT: You are making this far too complicated. Are you saying that it is proper, in your estimation, to bill for some reports that they file that show negative with abnormality and it's not proper to bill for other negative with abnormality depending on what the abnormality is?

MR. GAGLEARD: I would say no, it's not proper to bill under either circumstance unless – unless they have, with respect to the venous study, pictures of the abnormality that they can objectively make a determination whether it's there and, if so, to what extent potentially.

THE COURT: But that's true for the negative tests. [24] If they don't look at the still photographs or view the videotape, in your view they can't bill, correct?

MR. GAGLEARD: That's right.

THE COURT: Now, if it's a negative with an abnormality, no matter what the abnormality is and no matter what the conclusion is the doctor draws, again, your position would be as to those if they don't look at the still photographs or watch the videotape of the test, they shouldn't be permitted to bill, correct?

MR. GAGLEARD: That's true.

THE COURT: Now, what about the positive tests? You haven't included those in your case. In your estimation, is it appropriate to bill for a positive finding?

MR. GAGLEARD: Yes, because the positive tests, that is, positive for a deep venous thrombosis, has objective data that accompany the work sheet, you know, that is, you've got the video and you have the photographs. You have –

THE COURT: Well, let me make this more simple because this is what I'm trying to figure out. If a doctor looks at a work sheet and that's all, is it appropriate, in your estimation, under these regulations to bill for a positive finding?

MR. GAGLEARD: Assuming that hypothetical, the answer is no because they would have no clue and they would have to accept at face value what the technician or the [25] technologist is telling them.

THE COURT: So it's your assumption, then, that in the case of positive tests, they look at the work sheet and something else before they make the positive finding, but in the case of negative or negative with abnormality, they don't look at anything else.

MR. GAGLEARD: That's right.

THE COURT: Is that it? Okay.

Is there any dispute here as to whether the physicians that submitted these bills that you are seeking recovery for looked at the work sheet?

MR. GAGLEARD: No. I'll take them at face value.

THE COURT: I want to make sure that I understand what you are relying upon in support of the claim that the doctor was required to look at something more than the work sheet before he could bill under this government program. In no particular order, we have Swafford's opinion, right?

MR. GAGLEARD: Correct.

THE COURT: We have the three affidavits you filed.

MR. GAGLEARD: Yes, sir.

THE COURT: And we have the Carrier Manual that covers something else but you argue inferentially from, right?

MR. GAGLEARD: Yes, sir.

THE COURT: Anything else?

[26] MR. GAGLEARD: Yes, sir. If you look at Dean Swafford's affidavit, you also see statements attributed to, for example, the hospital and Dr. Jain, I believe, if I am recalling Dean's affidavit correct, that would reflect that their billing practice is in fact wrong, that is, he was told to keep it in-house, people get in trouble, don't go to the outside, and that's detailed in his affidavit that was filed in opposition to the motions as initially filed, and we simply just appended it again to this.

THE COURT: Let's assume that a doctor or an administrator in one or more of these hospitals or practices thought that there was a requirement to do something more. Why does that establish that in fact

something more was required as a matter of regulation or law?

MR. GAGLEARD: Well, I think it goes to the interpretation of the words, not asking for a legal – not asking for a legal definition, not asking for a legal opinion, that is, what everybody thought what was appropriate at the time.

– THE COURT: Now, Mr. Gagleard, if there were a bunch of affidavits filed by administrators that thought it was not necessary to do anything more than look at the work sheet, you would not consider that competent evidence as to what was or was not required, would you?

MR. GAGLEARD: Well, I would – I would say that [27] there is a difference – there is a difference as to who is saying what and –

THE COURT: Well, yeah. In one case it supports you and in the other it doesn't in my example.

MR. GAGLEARD: Right. And I'm not saying that because of that fact that we're right as a matter of law or, taking the court's example, that we are wrong as a matter of law. It is but yet one more item, so to speak, that is put into the mix.

THE COURT: Okay. So we've got Swafford's opinion, the affiant's Carrier Manual on another test, and the opinion of hospital administrators reflected in Swafford's affidavit. Is that it?

MR. GAGLEARD: That's true.

THE COURT: Is there anything else?

MR. GAGLEARD: That's true. You also have, if I'm recalling correctly, you also have the Provider Manual as well.

THE COURT: I thought there was general agreement that the Provider Manual didn't speak to this issue.

MR. GAGLEARD: Well, I believe that there was one part of that where they do speak to it, and let me see if I can find it in my notes real quick.

THE COURT: As to these tests or a different kind of test? I thought you clearly admitted in your pleadings that [28] there was no regulation in the Provider Manual that spelled out what the physician had to do in connection with billing for this service.

MR. GAGLEARD: Well, I think what we said is that there is nothing that says vascular surgeons – there is nothing that says specifically that you would consider to be a definition of the word "interpret," but I think when you look at this case as a whole, in a totality, the rules, whether they're in the Provider Manual or the Carrier Manual, clearly indicate that the technical component is nothing more than the running of the test.

THE COURT: Mr. Gagleard, I'm not asking for you to wave your arms or make an argument of some inference here or there. I just want to know what you are referring to that sets forth the requirement that you say exists.

Now, I thought that I understood you in your pleadings to agree that there was no such requirement in the Provider Manual but that there are what you believe to be

requirements in other sources, so all we're talking about right now, and then you can argue when I'm done about anything you want, is whether there's something in the Provider Manual that says that they have to do something more than looking at the work sheet.

MR. GAGLEARD: When you look at HCFA's response to Dr. Jain's – Dr. Jain's FOI request, you'll see that they [29] quote from the Provider Manual and you'll see that they indicate that the technical component does not require the expertise of a doctor and is only the actual performance of the test. That's per the Provider Handbook. So when you look at the Provider Handbook and you look at the regs, whether they're in the Provider Handbook or the Carriers Manual or in any of the bulletins, to believe that the word "interpret" means looking at what the technician writes, you know, on a work sheet, and to the extent that the technician or technologist doesn't address any or all of the five factors, whether the factors are positive or negative in particular, and then the physician assumes that, one, the protocol was followed in terms of the study being properly performed and, two, that the protocol was followed, that any and all of the five factors are negative, that's what we're really dealing with here.

THE COURT: Mr. Gagleard, this is not that hard a question to answer, and I'm going to try it one last time, and if you won't answer it, then I'm going to assume that there is nothing in the regulation that's provided to the physicians that makes such a requirement. You quote extensively from the Carrier Manual. You quote from cases. I don't see anything that you quote from that Provider Manual that says that they had to look at the

still photos or look at the video. Now, I understand you are making arguments about this means that, but [30] I don't see any reference to a portion of the Provider Manual that says that they were required to do what you were requiring to do. Am I right about that or am I wrong?

MR. GAGLEARD: I believe you are accurate. There is nothing that says that the radiologist – strike that. There's nothing that says that you have to look at the video or the photos.

THE COURT: Now, I was also curious about these affidavits that you filed, and without getting to the question of whether the affidavits should or should not be stricken, which is requested in at least one of these pleadings, I don't see any discussion of any standard of care that applies to vascular surgeons in two out of the three affidavits. Is that correct?

MR. GAGLEARD: I believe that's right.

THE COURT: Why don't they speak to the standard of care if its so clear that vascular surgeons were required to do this?

MR. GAGLEARD: Because the one affidavit is from a technologist, Frank West, and the other –

THE COURT: Well, so is Mr. Swafford. He is a technologist too. That doesn't stop him from expressing an opinion.

MR. GAGLEARD: He doesn't talk about the standard of care, Your Honor.

[31] THE COURT: Okay. So we are talking about standard of care versus an opinion on the regulations, right?

MR. GAGLEARD: Yes.

THE COURT: All right. So one of them is a technician.

MR. GAGLEARD: Technologist, Frank West, the former head of the certification group.

THE COURT: All right.

MR. GAGLEARD: The other is Dr. Schwartz, a vascular surgeon.

THE COURT: Why doesn't Dr. Schwartz opine what the standard of care is if this is so clear?

MR. GAGLEARD: I believe he indicates what is appropriate and not. I intentionally stayed away from, and I assume he did too, the words "standard of care." I'm not convinced that the standard of care is pertinent. However –

THE COURT: That may be your – so your answer is it doesn't matter?

MR. GAGLEARD: That's right.

THE COURT: Okay. Now, the third affidavit does speak to the standard of care, and what the defendants respond to is that that doctor apparently has not been a treating physician for some 15 years. Is that correct?

MR. GAGLEARD: He has a physical problem which keeps him out of the operating room.

[32] THE COURT: Is it correct that the third doctor who does offer an opinion as to the standard of care has not been a treating physician for 15 years? Yes? No?

MR. GAGLEARD: He works and he's active in the practice.

THE COURT: Is he a treating physician? Yes or no?

MR. GAGLEARD: I believe he is. He works at an office and I've contacted him there, and by the way Your Honor –

THE COURT: So you disagree –

MR. GAGLEARD: I'm sorry.

THE COURT: Keep it up and we're over, understand? You came in here 20 minutes late without calling, which doesn't start you off very well, and now you insist on trying to reformulate my questions and answer something else because apparently you think I'm stupid and that I'm going to miss that, and that is not working well so far. Do you understand?

MR. GAGLEARD: Yes, sir.

THE COURT: Now, the third doctor does opine as to the standard of care, and the defendants say I shouldn't look at that anyway because he hasn't treated patients for 15 years. Now, you believe that's incorrect, he does treat patients, rights?

MR. GAGLEARD: He does treat patients. He just [33] doesn't sit at home.

THE COURT: Doesn't what?

MR. GAGLEARD: Sit at home.

THE COURT: Which affidavit by number, if you remember right, is the third affidavit?

MR. GAGLEARD: If I understand the question correct, I would believe that that's Dr. Schwartz. That would be tab 22.

THE COURT: You describe Schwartz as the one that doesn't speak to the standard of care.

MR. GAGLEARD: Well, I say here in paragraph 7, In my opinion it is both the standard of care, and essential, that a qualified physician either personally perform the ultrasound, and then I basically go on and indicate that the physician – or he indicates, rather, that the physician should look at the underlying hard copy data.

THE COURT: Mr. Gagleard, I've read the affidavits and I've compared them, and one of the physicians refers to the standard of care and the other doesn't. I'm just simply trying to figure out which is which.

MR. GAGLEARD: That would be Dr. Schwartz, page 4, paragraph 7.

THE COURT: So when you said before that Dr. Schwartz didn't speak to the standard of care, you meant Dr. Clarkson, right?

[34] MR. GAGLEARD: No, Mr. Clarkson is not a physician, Your Honor. He is a former HCFA employee.

THE COURT: He's the technologist?

MR. GAGLEARD: No. Frank West is the technologist.

THE COURT: Okay. So the ones that don't speak to the standard of care are West and Clarkson.

MR. GAGLEARD: I believe that's right.

THE COURT: Neither of whom are doctors.

MR. GAGLEARD: That's right.

THE COURT: All right. So the only doctor, then that we have is Dr. Schwartz, and he does in paragraph 7 speak to the standard of care, correct?

MR. GAGLEARD: Yes, he does.

THE COURT: Now, what has he been doing these last 15 years, then, that the defendants, for whatever reason, seem to think means he hasn't been practicing?

MR. GAGLEARD: I think they just looked at his CV and decided that he was not working.

THE COURT: Well, the last thing that I can find that he's done that's shown in his curriculum vitae listed through December of 1985.

MR. GAGLEARD: No, sir. My – I'm sorry.

THE COURT: I'm just looking at paragraph 4 and 5 of the section of his vitae attached to the affidavit under Work Experience, and he was last in private practice in 1979 and he [35] was last with General and Vascular Surgery in December of '85. What do you understand he's done since he was with General and Vascular Surgery in 1985?

MR. GAGLEARD: Well, I'll read from paragraph 1, his affidavit: In part, I have been interpreting venous ultrasound studies and billing therefore, including Medicare/Medicaid patients over the years inclusive 1991 to date, so – and then he also says –

THE COURT: Who did he work for?

MR. GAGLEARD: I don't have that off the top of my head, Your Honor. I'm sorry.

THE COURT: I mean, there are some other groups that he lists under previous positions without any dates attached to them. Where do you contact this guy?

MR. GAGLEARD: At his office.

THE COURT: Which is located where?

MR. GAGLEARD: In the Toledo area.

THE COURT: Well, there are two – how do they answer the phone when you contact him?

MR. GAGLEARD: It's a physicians' office.

THE COURT: They say just "physicans' office"?

MR. GAGLEARD: I forgot the name of the office, Your Honor.

THE COURT: Is it Vascular Surgery of Northwestern Ohio?

[36] MR. GAGLEARD: I don't believe so.

THE COURT: Is it The Syldrum Medical Group?

MR. GAGLEARD: Your Honor, I don't want to give you inaccurate information, and to be perfectly

blunt, I've called him down there a few times, and it's just slipped my mind how they answer the phone, but it's a physicians group. I don't believe, in all fairness, that it's a vascular surgical group.

THE COURT: But he is with a group?

MR. GAGLEARD: Yes, sir.

THE COURT: And you don't know the name.

MR. GAGLEARD: I forgot the name. Totally slipped my mind.

THE COURT: The other thing that I thought was interesting about Dr. Schwartz's affidavit is that at no point does he say what he does. He says what his opinion is in terms of a doctor being permitted to bill for these, but he doesn't, for example, say I always read these studies or I sometimes read these studies or I never look at the work sheet by itself. I mean, don't you find that kind of curious inasmuch as that's the heart of this case?

MR. GAGLEARD: No, because he would have a difficult time saying the standard of care is to look at and then not view the video. If asked, he would say, I view the video.

THE COURT: Now, how does looking at a still [37] photograph tell you that a venous study was properly performed and that the information the technologist put on the work sheet was accurately recorded?

MR. GAGLEARD: Because if the study is not properly performed, you may tell from the color, that is, if the – if the Doppler was not – was not properly positioned, that may affect the color and probably would

affect the color. If there is a photograph, you would seen an obstruction. You would see the clot. That's presumably why they're taking the photograph. So when you have a positive study and you look at the photograph, giving the doctors the benefit of the doubt that, A, they're looking at the photograph and, B, the photograph is diagnostic, then the physician would see that there would be an abnormality.

THE COURT: Now I'm really confused because my understanding was that you look at these four characteristics of the veins and the responses that the veins exhibit to certain manipulations that you employ, and depending on how the veins respond to compression and other things, that collectively tells the doctor whether there is one of these DVT conditions, correct?

MR. GAGLEARD: Yes, sir.

THE COURT: Now, you are saying that if a still photo then shows a clot –

MR. GAGLEARD: It would show an obstruction.

[38] THE COURT: Well, why do they test these four different things if every picture shows whether there is or is not a clot? Doesn't make any sense.

MR. GAGLEARD: Well, no. That's the point. If you look at the photograph and there is an obstruction, the photograph is taken to depict the obstruction. If a photograph was taken, a series of photographs – by the way, it's not just one photograph relative to a negative study, let's say, but there are a series of photographs that are taken, representative photographs that were taken,

and you would not see, based on those photographs, evidence of obstruction in a study that's been reported as negative.

THE COURT: So you're not going to see the obstruction; you're going to see the responses to the manipulation that the technician sees from which ultimately a conclusion is drawn as to whether there is or is not an obstruction. Is that a better way to phrase it?

MR. GAGLEARD: Probably. You would see an objective basis relative to that obstruction.

THE COURT: All right. You're going to see what the technician then presumably recorded on the work sheet.

MR. GAGLEARD: Yes, sir. So that you could make, you meaning the doctor, could make an independent judgment whether what the technician reported was in fact occurring.

THE COURT: All right. I think those are all of the [39] questions that I had. Anything else you want to tell me?

MR. GAGLEARD: Well, I don't think that this is an issue of scientific judgment. I think that this is not an issue, would you be better off performing the test in another way, like the *Luckey*, case, or are you better off performing an additional study to give you the same information. The issue in this case is as a matter of law do the defendants carry the day by saying the work sheet is the result of the study. It's not a legal issue. It's not a legal conclusion – or not calling for a legal conclusion but,

rather, whether the work sheet itself is the, quote, result of the study.

Now, it seems to me, as is evidenced through the various documents and materials we've given you both from the Providers Handbook and the Carriers Handbook and the bulletins, that the result of the study is not the work sheet but it's the result of the study itself, that is, the hard copy data underlying the study, whether you want to call it a video or whether you want to call it a photograph. Their whole claim is that the work sheet is the result of the study, and there's nothing that says that their client has to do anything other than look at the technician's work sheet and assume that if one or more of the factors are not addressed in the work sheet, that the study was conducted according to protocol and further assume that any or all of those factors are negative.

[40] THE COURT: Would it be appropriate for the doctor to bill if the doctor looked at the work sheet and the series of still photographs?

MR. GAGLEARD: Yes.

THE COURT: Now, why is the work sheet any different than the still photographs in terms of your conclusion that the work sheet is not the or even a result of the study?

MR. GAGLEARD: Because the work sheet is not the objective basis from which the doctor can make an independent judgment one way or the other as to whether – what the technician is reporting is accurate.

THE COURT: Well, it seems to me when you get into that argument you are making what really is a

multifaceted argument. One is that the doctors are acting improperly in charging for this service to the government, but if it's improper for the doctors to draw a conclusion looking only at the work sheet, are you not essentially contending that they've all committed malpractice, then, anytime that it turns out their ultimate conclusion was wrong because they relied only on the work sheet?

MR. GAGLEARD: Let's put it this way. I would love to be the plaintiff's lawyer in that type of case for the doctor to get up on the witness stand and say, I never looked at the study, never looked at the photos or there are were no photos, and I never looked at the video, and I have a [41] technician's work sheet that was reported negative for DVT, and, oh, by the way, the patient threw a clot two days later.

THE COURT: I didn't ask you whether you'd like to handle one of these cases. I asked you whether essentially you are saying that all of the vascular surgeons in this town were committing malpractice when they looked only at the work sheet.

MR. GAGLEARD: I would say yes.

THE COURT: Does it strike you as odd that you had to go to Ohio to find a doctor that would say that, whose vitae at least suggests he hasn't practiced since 1985?

MR. GAGLEARD: No.

THE COURT: Why is that if this is so clear-cut, in your opinion?

MR. GAGLEARD: Because, doing a fair amount of medical malpractice work myself, not a lot but a fair amount, I can tell you that it's very difficult, especially in a specialty like vascular surgery, to obtain a local expert, and that's especially true – maybe to digress a little bit, but it's very difficult, if not darn near impossible, to get somebody from U of M to testify on behalf of a plaintiff in a medical malpractice case, and I would say essentially the same thing down at the medical center inclusive of Wayne State.

THE COURT: All right.

MR. GAGLEARD: So that issue, I think, with all due [42] respect, is a nonissue in terms of the location of Dr. Schwartz.

THE COURT: I understand your argument.

MR. GAGLEARD: So they then make that assumption and then they go so far as to argue in their brief that they're performing a service because they can imagine what the veins must have looked like when they're not addressed and they don't look at anything.

We also have the survey where 10 different institutions from a variety of places all indicated that you've got to have one or the other even for a negative study. You've got to have video and at least a doctor has to look at the prints.

THE COURT: You are surely not suggesting that what Swafford says in an affidavit he was told by other hospitals is competent evidence for this purpose, are you?

MR. GAGLEARD: Well, yes, I am.

THE COURT: It's either hearsay or it's not hearsay because it's not offered for the truth of the matter asserted, and if it's not offered for the truth of the matter asserted, then it's irrelevant.

MR. GAGLEARD: It was provided to Borgess, a defendant, and Borgess acted on it. Borgess changed –

THE COURT: Why does that make it any less hearsay?

MR. GAGLEARD: Because they're a defendant and it's [43] an admission.

THE COURT: Whether they changed their procedure does not seem to be disputed here. There is no admission that they changed it because of what Swafford learned in his study, but even if you assume that they did, why does that make what he was told by 10 other hospital representatives anything other than hearsay?

MR. GAGLEARD: Because the hearsay is he was told by these other institutions, 10 of them, that they either have the video and/or they have the prints, even for a negative study.

THE COURT: Right.

MR. GAGLEARD: The issue before was Borgess said, No, no, no, we don't need the prints for the negative study. The doctors can – I'm sorry. Oh, okay.

THE COURT: I wasn't asking anything.

MR. GAGLEARD: All right. We don't need the prints for the negative study, and the dispute that Dean was embroiled in for this period of time, for a rather long

period of time, was the technicians are providing a work sheet, and when the study is negative, the doctors don't look at the video, they don't look at any hard copy data, and all they're doing is looking at the work sheet. The hospital said, Okay, do this survey, and see what other institutions around are doing or what their practice is – excuse me – relative to [44] negative studies, negative venous ultrasound studies, whether they also have prints that are provided to the doctor, even for a negative study, which provides the doctor with an objective basis from which to make a decision and to make an interpretation. After they got the results of the study, the hospital, through the vascular panel, whom I believe was headed by defendant Dr. Collins, approved and incorporated the change.

THE COURT: This is a simple question that either you are missing or I'm missing. How does what Mr. Swafford was told by other hospitals not fall squarely within the hearsay rule?

MR. GAGLEARD: For two reasons. One, he was an agent of Borgess Hospital at the time. Two –

THE COURT: That means what he said would not be hearsay. What somebody says to him is still squarely hearsay –

MR. GAGLEARD: I agree.

THE COURT: – unless you've got a new reading of 801.

MR. GAGLEARD: No, sir, I don't believe I do. No.

THE COURT: So the fact that they were told to an agent of the hospital doesn't make them any less hearsay, so what's your second attempt at making this not be hearsay?

MR. GAGLEARD: The hospital acted on not only what [45] Mr. Swafford told them, but I believe there was at least one other tech, I think Kristin Mohney, if memory serves me right, that provided the same information.

THE COURT: Mr. Gagleard, if that's your whole answer, I would suggest that if this case goes to trial, you probably better research that because it's not coming in through Mr. Swafford. It's hearsay. It's being offered for the truth of the matter asserted. It does not fall within any exception that I am aware of and it does not fall within any exception that you've cited to me, so move on.

MR. GAGLEARD: Okay. By the way, it still might come in under state of mind –

THE COURT: Move on.

MR. GAGLEARD: All right. I spend a fair amount of time in the brief indicating to the court why it's important that the doctor review the objective data underlying the study.

THE COURT: Let's concede that it's important. Let's concede they should have. The question is whether, having failed to do so, they violated the False Claims Act. The False Claims Act doesn't set forth a standard of medical practice. It sets forth a standard people have to meet in order to get money from the government.

MR. GAGLEARD: I agree.

THE COURT: Let's assume the better practice was to [46] look at the stills and/or the video. That seems like a logical assumption to make if the hospital changed their practices or their protocols in 1997 to so require. Now, what makes the failure to have done so false when bills were submitted?

MR. GAGLEARD: If you look at the 26 Modifier, if you look at what the technical component is, when you look at what a professional component is, and when you look at the various HCFA, whether you call them in the Carriers Manual or the Providers Manual, you come away with that the doctor has to provide a discrete, identifiable service, and for the doctors to win this case they have – certainly to win this motion they have to convince you that as a matter of law there was – a reasonable interpretation is that a result of the study means the technician's work sheet. That is a result of the study.

THE COURT: You're wandering all around what the issue is here, it seems to me. Whether they performed a discrete, identifiable service, it seems to me, is easy. They did perform a discrete, identifiable service. They looked at the work sheet.

Now, the only reason that summary judgment wasn't granted earlier was the hospitals were simply unwilling to answer what seemed to be a simple question, and that is what did they do. Now we know what they did. I'm not worried for [47] purposes of this ruling about whether in some instances they actually did look at the still photos and the charts and/or the video because I

don't understand those instances to come within what you contend are false claims to start with, correct?

MR. GAGLEARD: Correct.

THE COURT: You are only saying the claims were false if they didn't look at anything else, if they just looked at the work sheet, right?

MR. GAGLEARD: That's true.

THE COURT: Now, if they hadn't done anything at all, then it would seem to me that's a simple case for you; you win. Here they did perform a discrete, identifiable service; they looked at the work sheet. Now, whether that was sufficient for billing purposes under the regulations then becomes the question. We know what they did. The question is was that enough to justify billing. Do you disagree with that analysis?

MR. GAGLEARD: No, but let me add one more thing. You have to add the words without the interposition of the judgment of a third person.

THE COURT: Well, that is one of the reasons why, then, the question is whether that function in fact comports with the regulations for billing purposes, correct?

MR. GAGLEARD: Yes, sir. And what we're saying is, [48] contrary to what the defendants are saying – the defendants are saying this is a binary study, meaning it's either positive or negative, it's all objective, and so on and so forth. We are disagreeing with that. We're saying that when you perform the five maneuvers, whether it's compressibility, augmentation, so on and so forth, that

the physician is the one who needs to look at the objective data to make that determination. Otherwise, it's the technician or the technologist that is in fact making that judgment.

Now, at the depositions – I'm sure you read them, but there was a lot of quibbling about, well, is it a technician which is rendering a reading or is the technician rendering an interpretation, and there was a lot of discussion about that. The fact of the matter is the technician is rendering an interpretation. They can call it a reading, they can call it whatever fancy word they want to use, but it's still an interpretation. When the doctor looks at the work sheet, the doctor has – is believing that the technician found all these different things and interpreted all these different things and is assuming that they're accurate. The doctor has no objective basis whatsoever to draw his or her own conclusions. By definition, the doctor has to accept and is accepting what the technician writes, and I believe that when you look at the Provider Handbook, and I believe it's our Exhibit 20, under Technical Component it says, does not [49] require the expertise of a physician, and that's exactly what the doctors have put the technicians in. They put them in a position of having to make an interpretation of what the ultrasound study shows one way or the other.

I don't know if Your Honor – I don't know if Your Honor has any questions, but let me just –

THE COURT: I do have one other question. I was just flipping back through your 30 pages of your brief while you were pausing to see if you had found any case under the False Claims Act where a doctor had

actually done something and billed for it but then was held liable under the False Claims Act based upon an argument that that particular service wasn't sufficient or didn't go far enough or didn't employ the proper medical – didn't meet what the False Claims Act claimant contended was required by the standard of practice. I don't find any case of all of the cases that have come down under the False Claims Act that you rely upon in connection with these claims. Am I missing something here?

MR. GAGLEARD: I don't believe you are.

THE COURT: So it's clear, you found no case where the doctor actually did perform a service where the doctor was found liable under the False Claims Act because it was held that the nature of the service didn't comport with regulations.

MR. GAGLEARD: I don't recall any, Your Honor.

[50] THE COURT: All right. That's helpful. Thank you.

MR. GAGLEARD: Thank you. Lastly, I would say a venous ultrasound study is a radiographic – a radiology study. What the defendants are saying is that they could perform – they can do what they do, and that's fine, but a radiologist couldn't. A radiologist would have a problem in filing a false claim because they claim that a number of the discussions and comments under the various sections that we cited are directed towards the radiologist and not them. So now you almost have – not almost, you do. You have a two-tiered system. You have the same act. One is performed by a vascular surgeon.

According to the defendants, that's okay, not a false claim. You have the same act performed by a radiologist, and that would be a false claim.

THE COURT: Well, my assumption has been that the discussion about radiology services has probably been prompted by the fact that, if I remember right, I asked about how what happened in the case of these venous studies compares with radiology in, I believe, the very first Rule 16 conference that we held off the record in this case. My understanding is that in order to bill for a radiologist's services, the radiologist has to actually look at the x-rays, correct?

MR. GAGLEARD: That's it. Yes, sir.

THE COURT: Now, the regulations require the radiologist to look at the x-rays, do they not?

[51] MR. GAGLEARD: As well as the venous ultrasound, that's right.

THE COURT: The regulations do not say that you have to look at the venous ultrasound or the still photos. I understand what your argument is that they should be interpreted to require, but they don't say that.

Now, the regulations themselves say you have to look at the x-ray to bill for radiology services, do they not?

MR. GAGLEARD: I believe they do, as well as –

THE COURT: Now, am I correct in assuming that in the field of radiology apparently there is not a practice, and whether it's good or bad we will put aside for a moment, of radiologists using technicians to fill out

work sheets that put down what the technologist sees when the x-ray is taken? Would that be correct?

MR. GAGLEARD: I don't know that that's entirely accurate, Your Honor.

THE COURT: Well, do – that wasn't my most articulate question. Obviously, there are technicians that actually use the x-ray machine to take the x-ray pictures, correct?

MR. GAGLEARD: Of course.

THE COURT: If we assume that they're called x-ray technicians, just like these folks here are called venous technicians –

[52] MR. GAGLEARD: Vascular.

THE COURT: – vascular technicians, is there a practice where radiology technicians prepare a work sheet that in any way describes what's on the x-ray?

MR. GAGLEARD: There are work sheets that are in fact provided.

THE COURT: What do the work sheets say or show? Do you know?

MR. GAGLEARD: It will show what the film was. It will provide maybe some historical data.

THE COURT: I understand there must be something that accompanies the x-ray film itself that at a minimum says whose body part was being x-rayed, when it was taken, probably something about the x-ray machine and how the exposures were taken and the name of the technologist. Would that be a correct assumption?

MR. GAGLEARD: Yes, sir.

THE COURT: Now, is there anything on an x-ray technologist's sheet that's similar to the four or five findings that a venous technician – or vascular technician puts on the work sheets that the doctors in this case looked at?

MR. GAGLEARD: My understanding is yes. My understanding, I believe at Borgess, is that the answer is yes.

[53] THE COURT: At least that hospital uses a similar technique in connection with –

MR. GAGLEARD: That's my understanding.

THE COURT: Now, what you are really arguing here, are you not, is that because one or more of these manuals required x-ray – that required radiologists to do more than look at the x-ray technicians' work sheets and they had to actually look at the x-ray themselves, that therefore vascular surgeons were required to do that in connection with vascular studies?

MR. GAGLEARD: That's certainly one of the reasons and bases, that's correct, Your Honor.

THE COURT: All right. I got it. So it's clear, then, that in drafting these regulations, if HCFA or whoever drafts these things wanted to require the doctor to perform a certain specific task in order to justify billing for vascular services, they knew how to do it as illustrated by how they drafted the regulations in connection with radiology services, correct?

MR. GAGLEARD: I would argue that it's the same. I would argue –

THE COURT: I know you would argue that, but the language is clearly not the same in the regulations, correct?

MR. GAGLEARD: And I think Your Honor is assuming that the venous ultrasound study, when it's interpreted by a [54] vascular surgeon, is not a radiographic or radiology study. I'm saying it's a radiology study, and certainly as such, according to their position, it's okay.

THE COURT: Is it billed under the same code as a radiology study?

MR. GAGLEARD: Sometimes it is and sometimes it's not.

THE COURT: So a vascular surgeon gets the same fee for whatever they do, whether they read the work sheet or whether, as you contend they were required to do, they actually look at the videotape, they get the same fee as a radiologist gets for reading an x-ray?

MR. GAGLEARD: An x-ray or reading the same venous ultrasound study?

THE COURT: No. I'm asking about x-rays.

MR. GAGLEARD: I can't – I can't give you a definitive answer to that question, Your Honor.

THE COURT: So we don't know if it comes under the same regulation. I mean, in terms of that answer you don't know, right?

MR. GAGLEARD: That's true.

THE COURT: Okay. Anything else you want to tell me?

MR. GAGLEARD: I think that's it, Your Honor.

THE COURT: Any quick response? It seems to me [55] we've covered the waterfront here. Mr. Smith?

MR. SMITH: Unless the court has any questions, I have nothing to add.

THE COURT: Mr. French?

MR. FRENCH: Nothing to add. Thank you.

THE COURT: Mr. Lloyd?

MR. LLOYD: Nothing, Your Honor.

THE COURT: All right. Interesting question. I think we've finally now gotten down to the bottom of what the vascular surgeons actually do and the basis upon the plaintiff's contention that they didn't do enough to justify the billing. The court will go back and look at this matter one more time in light of the arguments here this afternoon and the answers to the court's questions and take the matter under advisement pending a written opinion.

I appreciate the excellent extensive briefs and your answers to the court's questions here this afternoon. Thank you very much.

(Proceedings concluded at 3:17 P.M.)

[56] REPORTER'S CERTIFICATE

I, Sharon E. Fox, Official Court Reporter for the United States District Court for the Western District of Michigan, appointed pursuant to the provisions of Title 28, United States Code, Section 753, do hereby certify that on the date hereinbefore set forth I reported stenographically the proceedings had in the within-entitled and numbered cause; and I do further certify that the proceedings were transcribed by me with the use of computer-aided transcription under my direction and supervision and that the foregoing is a full, true, and accurate transcript of my original stenotype notes.

/s/ Sharon E. Fox
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No. 01-1399

In the Supreme Court of the United States

UNITED STATES OF AMERICA, EX REL.
JACK OBEYDEAN SWAFFORD, A/K/A DEAN J. SWAFFORD,
Petitioner,

v.

BORGESS MEDICAL CENTER,
A NONPROFIT MICHIGAN CORPORATION, ET AL.,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. Whether in the absence of a circuit split or departure from Supreme Court precedent, this Court should review the District Court and Sixth Circuit decisions that mere non-compliance with health care regulations or a requisite standard of care is insufficient on its own to establish "falsity" under the False Claims Act.

2. Whether in the absence of a circuit split or departure from Supreme Court precedent, this Court should review the District Court and Sixth Circuit decisions that the ultrasound reports in this case were not knowingly fraudulent.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondent Borgess Medical Center makes the following disclosure:

Borgess Medical Center is a non-profit corporation. No publicly-owned corporation owns stock in Borgess Medical Center.

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RESPONDENT BORGESS MEDICAL CENTER'S STATEMENT OF THE CASE

This is a qui tam action brought pursuant to 31 U.S.C. § 3729-3731, known as the False Claims Act (hereinafter, "FCA"). Petitioner alleges that Respondents have submitted false claims to the federal government for Respondent physicians' reading and interpretation of venous Doppler ultrasound tests conducted on patients who were participants in federal health care programs. These tests are designed to assist in the diagnosis of deep vein thrombosis ("DVT") or blood clots in the arms and legs.

Petitioner's statement of the proceedings below in this case is accurate. Pet. at 4. However, Respondent Borgess Medical Center wishes to describe the ultrasound studies which provide the basis for Petitioner's claim, as Petitioner's description of these studies is misleading.

Understanding the way in which venous ultrasound studies are performed is crucial to this case. For patients suspected of suffering from risk factors for blood clots, defendant physicians would order a venous ultrasound study. Using ultrasound, the patient's venous system would be examined to determine the presence or absence of certain "normal" characteristics for five blood clot risk factors. Either a technician or a technologist would typically perform the ultrasound study, and would indicate the presence or absence of the five factors on a worksheet. The worksheet was then given to a physician for review and interpretation.

Although the five factors of the studies are focused on obtaining a "negative" or "positive" finding, the overall results of the studies include significant variations from patient to patient. Some studies are incomplete because of

limitations on the technician's ability to test all of the areas required; some studies indicate evidence of non-blood clot related pathologies or abnormalities; some studies show "positive" characteristics consistent with the presence of acute blood clots; and some studies reveal no abnormalities whatsoever.

Technicians are highly skilled in performing the studies. However, more than technical knowledge is required to understand the medical significance of these variations. Consequently, vascular surgeons would review every test–from simple to complex–to ensure that the results were evaluated by a physician qualified to see the medical significance of the various possible outcomes.

In those cases where technicians found abnormal responses–described as a test that is "positive" for possible DVT–the physicians reviewed the videotape (or still photographs derived from the videotape) of the ultrasound test. In cases where the technicians found normal responses–a so-called "negative" test for possible DVT–videotapes or stills were not routinely reviewed. Where the technicians found normal responses, but other abnormalities existed, the vascular physicians might or might not review the videotapes or stills, depending on the abnormality.

Petitioner characterizes as "plagiarism" the physician reports which were based on technician worksheets alone, where physicians did not deem the review of videotapes or stills necessary. Pet. at 3. Petitioner bases his FCA claim on this alleged "plagiarism."

REASONS FOR DENYING THE WRIT OF CERTIORARI

I Petitioner's argument for the importance of the instant case is unpersuasive.

Rule 10 of the Supreme Court Rules indicates "the character of the reasons the Court considers" when reviewing a petition for certiorari. SUP. CT. R. 10. The reasons applicable to this case are:

> (1) a conflict between United States courts of appeals on an important matter,
>
> (2) an unusual departure from the accepted course of judicial proceedings warranting an exercise of supervisory power,
>
> (3) a United States court of appeals has decided an important federal question in conflict with relevant Supreme Court jurisprudence, and
>
> (4) a United States court of appeals has decided an important question of federal law that has not been, but should be, settled by this Court.

SUP. CT. R. 10 (a), (c).

Importantly, Petitioner in this case does not allege a circuit split or a conflict with Supreme Court jurisprudence; this case clearly involves neither. Petitioner argues somewhat implicitly that this case involves an important question of

federal law that has not been but should be settled by this Court. Unfortunately for Petitioner, the content of this important federal question is never made clear in the Petition.

In arguing for the "importance" of this case, Petitioner first cites Wright and Miller's *Federal Practice and Procedure* for the proposition that summary judgment is disfavored in matters involving important public issues. Pet. at 5. However, to argue that review is appropriate for any case dismissed on summary judgment which involves an important public issue would be to cast the net of discretionary review wide indeed. Even if it were generally accepted that summary judgment is disfavored in matters involving important public issues, the question should be why the Court should review *this particular* case dismissed on summary judgment below. Petitioner offers no answer to this question.

Petitioner next argues that this case merits review because the "the detection and eradication of health care fraud and abuse is [sic] a top priority of federal law enforcement." Pet at 6 (citing *The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for FY 1998*). This proposition is uncontroversial. And yet, it too fails to provide a basis for granting review. For to state that this case involves a matter that is a top priority of federal law enforcement is not to distinguish this case in any way from hundreds of others, all of which cannot be reviewed by this Court. To grant review to all cases involving health care fraud–even cases which were dismissed on summary judgment below–would all but eviscerate this Court's discretionary review.

Perhaps recognizing the over-inclusiveness of his first two arguments, Petitioner next attempts to articulate a more specific question of federal law deserving review. As explained in more detail in Section III below, Petitioner in this case claims that the services for which Respondent physicians billed for the reading of "negative" DVT studies fail to meet the definition of "physician's services," as defined by applicable federal regulations and by the applicable medical standard of care. Petitioner specifically finds fault with vascular physicians' use of Medicare billing codes with "26 modifiers" when billing for the services at issue in this case. "26 modifiers" indicate that the physician delivered the "professional," as distinct from the "technical" component of the test. In Petitioner's view, the claims in this case were "false" or "fraudulent" because vascular physicians did not provide any service, "professional" or otherwise, in reading the negative DVT studies.

In this context, Petitioner urges this court to grant review because: "THERE IS NO RELEVANT PRECEDENT FOR INTERPRETING HEALTH CARE BILLING CODES, WHERE NO DEFINITION HAS BEEN PROVIDED BY THE FEDERAL GOVERNMENT." Pet. at 7. (emphasis original) Without the review requested, Petitioner argues, health care providers will "continue" with impunity to bill the federal government for services that do not meet the definition of such services in the healthcare community. *Id.* at 8.

First, Petitioner's argument misconstrues the role of this Court. Petitioner appears to request that this court grant a writ of certiorari in order to give guidance on the definition of such terms as "physician services," "professional services," and/or "reading" and "interpretation" of test results. These terms are, by Petitioner's own account,

defined by a number of federal rules and regulations. *See* Pet at 17.[1] To the extent that these definitions are problematic, it is the role of the executive and the legislative branches, not the judiciary, to amend the relevant regulations.

Second, Petitioner's argument undermines his allegation elsewhere that the claims involved in this case were "false" in any relevant sense of the word. Petitioner asserts that the federal government has provided no meaningful guidance on the use of certain billing codes and terms used to describe the services rendered in this case (e.g. "physician services," "professional services"). Pet. at 7. Petitioner consequently urges this Court to provide guidance on these codes and terms. *Id.* But how can Petitioner allege that Respondent's requests for payment for physician or professional services were "false" or "fraudulent" where the terms "physician" and "professional services" were nowhere clearly defined? In other words, how can Respondent have known, in any actionable sense, that physicians were not performing billable services, when there was no accepted definition of what billable services actually were? In essence, Petitioner asks the Court to grant review in order to define Medicare billing terms, so that Respondent may, *ex post facto*, be held responsible for understanding and disregarding these definitions when billing. Such a request is hard to understand.

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[1] Petitioner below urged the application of the Health Care Financing Administration's Carriers Manual, and several alternative regulations. The District Court found that none applied to this case. *See* District Court Opinion, Pet's App. A at 11a-12a (42 C.F.R. § 415; 60 C.F.R. § 63142; 42 C.F.R. §§ 415.102, 415.120, 415.130, 1395; and 60 C.F.R. § 63130-63133 not applicable).

Finally, Petitioner complains of an alleged discovery error in the District Court. Petitioner's argument is meritless, for the reason explicated in Section II below.

At bottom, Petitioner cannot generate importance where none exists. While the instant case deals with alleged health care fraud, and was dismissed on summary judgment below, these features do not in and of themselves make this case appropriate for review. Nor does the speculation that review of this case could--or should--provide regulatory guidance in the health care arena. Because Petitioner does not carry his burden of demonstrating any important federal question, or demonstrating that the case should be reviewed on any other grounds, Respondent requests that the writ of certiorari be denied.

II The District Court's alleged discovery error did not prejudice petitioner's case.

To prevail under the FCA, a plaintiff must establish: (1) that the defendant knowingly presented a claim to the United States for payment or approval; (2) that the claim was false or fraudulent; and (3) that the defendant "knew" that the claim was false or fraudulent. 31 U.S.C. §3729(a).[2]

Petitioner alleges that he was not permitted to conduct discovery on the issue of the third element, whether the

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[2] The first element, the submission of a claim, has never been in dispute in this case. The second and third elements have been in dispute, and shall be discussed in Sections III and IV below, respectively.

defendant "knew" that the claim was false or fraudulent. This element is commonly called the "scienter" element. Specifically, Petitioner alleges that the District Court, by Order of March 29, 1999, *see* Pet's App. D, directed the parties to embark on an "initial" phase of discovery dealing only with the physicians' interpretation practices. The District Court then went on to grant plaintiff summary judgment in part on the grounds that Petitioner had failed to make a showing of scienter, that is, of "reckless disregard" or "deliberate ignorance" with respect to the falsity of its claims. Pet. at 9 (citing District Court Opinion, Pet's App. A at 22a).

This alleged discovery error objection can be disposed of summarily. Even if the District Court erred in making findings regarding scienter (which Respondent in no way concedes), the District Court's summary judgment relied not merely on Petitioner's failure to demonstrate a genuine issue of material fact with respect to scienter but also–in fact, predominantly–on Petitioner's failure with respect to the second element of a FCA claim, falsity. In fact, the District Court opinion discusses the second element of the case, falsity, for nearly twelve pages, and the third element, scienter, for fewer than three. *See* District Court Opinion, Pet's App. A at 21a-23a (scienter) 9a-21a (falsity).

The District Court's so-called "error," even if substantiated, would therefore not affect the outcome of this case, and should be of little consequence to this Court. *See* FED. R. CIV. P. 61; 28 U.S.C. § 2111 ("On the hearing of any appeal or writ of certiorari in any case, the court shall give judgment after the examination of the record without regard to errors or defects which do not affect the substantial rights of the parties."); *Mraovic v. Elgin, Joliet & Eastern Ry. Co.*, 897 F.2d 268, 271 (7th Cir. 1990) (medical expert's testimony excluded but harmless since jury found no liability

and never got to damages aspect of case). Petitioner's argument that review should be granted based on a discovery error should thus be rejected.

III The District Court did not err in its decisions regarding the "falsity" of Respondent's claims.

With respect to the second element of the FCA, that the submitted claims were false or fraudulent, Petitioner faults the District Court for relying on two premises Petitioner considers erroneous:

> (1) that "the federal government had not published rules and/or regulations relative [sic] to the Respondents," and
>
> (2) that in establishing "falsity" under the False Claims Act "reference to the attending Standard of Practice was irrelevant."

Pet. at 12. Petitioner argues that these erroneous premises allowed the District Court to conclude that there was no genuine issue of material fact with respect to falsity. Pet. at 12.

A. The Inapplicability of Federal Regulations

Petitioner fails to realize that the first premise, even if erroneous, was not necessary to, and therefore does not undermine, the District Court's summary judgment for Respondent Borgess Medical Center. Petitioner is correct that the District Court found that the the Health Care Financing Administration's Carriers Manual, and several alternative regulations cited by Petitioner, did not apply to the

instant case. *See* District Court Opinion, Pet's App. A at 11a-12a (42 C.F.R. § 415; 60 C.F.R. § 63142; 42 C.F.R. §§ 415.102, 415.120, 415.130, 1395; and 60 C.F.R. § 63130-63133 not applicable). However, the District Court went on to hold that, even if these regulations governed Respondent's conduct, the "FCA is not an appropriate vehicle for policing technical compliance with administrative regulations," and that "[m]ere violations of administrative regulations are not actionable under the FCA 'unless the violator knowingly lies to the government about them.'" District Court Opinion, Pet's App. A at 12a (quoting *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999)).

Thus, the District Court opinion shows that summary judgment regarding falsity did not depend upon the inapplicability of the regulations cited by Petitioner. Rather, the District Court depended upon the unassailable legal proposition that regulatory non-compliance does not constitute "falsity" under the FCA.[3]

Petitioner's analysis of the applicability of certain regulations is an attempt to distract the Court from this unassailable proposition. As indicated above, the District Court relied upon *Lamers* in support of this proposition. But there are many more cases offering support. *See Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 733 (7th Cir. 1999) (holding that defendant had not violated any regulation, but

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[3/] Petitioner cites *Jones v. United States,* 121 F.3d 1327 (9th Cir. 1997), in support of the proposition that "publication [of regulations] in the Federal Register is legally sufficient notice to all interested or affected persons regardless of actual knowledge or hardship resulting from ignorance." Pet. at 17 (citing *Jones*). Because violation of regulations, noticed or not, does not constitute "falsity" under the FCA, this line of analysis is not fruitful.

even if he had, "technical violations of a federal regulation on which a claim is based do not make the claim 'false'"); *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996) ("Mere regulatory violations do not give rise to a viable FCA action."); *U.S. ex rel. Mikes v. Straus,* 84 F.Supp. 2d 427, 435-6 (S.D.N.Y. 1999) (rejecting plaintiff's theory that falsity could be based on defendant's non-compliance with a Medicare regulation).

Notably, Petitioner nowhere finds fault with the District Court's reliance on the rule for which these cases stand, despite the fact that it was this rule–and not the inapplicability of certain regulations–that was fatal to Petitioner's FCA claim in the District Court. Instead, Petitioner attempts to generate interest in this case by focusing on an issue on which there may be controversy, but which is not even arguably dispositive. Petitioner's attempt is transparent, and is not a proper basis for granting review.

B. The "Irrelevance" of the Standard of Care

The second premise with which Petitioner takes issue is that the District Court supposedly found "reference to the attending Standard of Practice was irrelevant" to a finding of falsity under the FCA. Pet. at 12. Petitioner argues that "[c]ontrary to the conclusion of the district court[,] reference to the attending Standard of Practice can be utilized to determine the falsity of a claim." Pet. at 21. Petitioner cites one case, *U.S. v. NHC Healthcare Corp.*, 115 F.Supp. 2d 1149 (W.D. Mo., 2000), in support of this proposition

Even a cursory reading of the District Court opinion in the instant case indicates that Petitioner has grossly mistated the District Court's decision with respect to the standard of care. Nowhere does the District Court state that

the standard of care or standard of practice in the medical community would be "irrelevant" or unimportant to a FCA claim brought in the context of patient care. Rather, the District Court opinion relies on the very different proposition, amply supported in case law, that claims that merely fail to meet the relevant standard of care are "insufficient" to establish falsity under the FCA. District Court Opinion, Pet's App. A at 16a-19a (citing *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730 (7th Cir. 1999); *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1998); *United States ex. rel. Hopper v. Anton*, 91 F.3d 1261 (9th Cir. 1996); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997); *U.S. ex rel. Mikes v. Straus*, 84 F.Supp 2d 427 (S.D.N.Y. 1999) ("submitting a claim to the Government for a service that was not provided in accordance with the relevant standard of care, however, without more, does not render that claim false or fraudulent for FCA purposes."))

The proposition that the standard of care is "irrelevant" to falsity and the proposition that non-compliance with the standard of care is insufficient to establish falsity are entirely distinct. But again, Petitioner attempts to generate interest in this case by pretending there is controversy where there is not. By mischaracterizing the District Court's conclusion regarding the standard of care, Petitioner paints the picture of a district court as impractical as it is overreaching, for to find that the applicable standard of care is entirely irrelevant to FCA claims involving patient care would be strange indeed. In fact, Petitioner attacks a straw man, for the District Court never states that the standard of care is irrelevant.

As mentioned above, in the context of this attack, Petitioner cites *U.S. v. NHC Healthcare Corp.*, 115 F.Supp.

2d 1149 (W.D. Mo., 2000) in support of the proposition that "reference to the attending Standard of Practice can be utilized to determine the falsity of a claim." Pet. at 21. Although Petitioner quotes *NHC* selectively, a more thorough reading of *NHC* hurts Petitioner more than it helps him.

In *NHC*, the government argued that the defendant nursing home was so severely understaffed that it could not possibly have administered all of the care it was obligated to perform under the Medicare and Medicaid programs for two nursing home residents for whose care the home had billed the government. The District Court for the Western District of Missouri held that plaintiff could state a claim for false or fraudulent billing for the two residents where they "were not provided the quality of care which promotes the maintenance and the enhancement of the quality of life." *NHC Healthcare*, 115 F.Supp.2d at 1152.[4]

What Petitioner fails to mention about *NHC* is that the opinion in that case takes pains to distinguish the main issue there--whether services such as bathing, turning, and administering drugs to patients were performed *at all*, under any definition of those terms--from the main issue of cases such as the instant one, where plaintiffs allege that services, which were admittedly performed, were not performed within the parameters set by the relevant standard of care.[5]

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[4] The court admitted that this was "an amorphous standard in need of further clarification," *id.*, but stated that at that stage in the litigation, a motion to dismiss for failure to state a claim, plaintiff need only plead a sufficient cause of action. *Id.*

[5] *NHC* utilizes *U.S. ex rel. Mikes v. Straus, supra,* and *U.S. ex rel Aranda v. Community Psychiatric Centers of Oklahoma, Inc.* 945

The *NHC* case articulates this crucial distinction in two helpful ways. First, the court explains:

> While the standard of care is raised in [those cases] and in the present case, it is discussed for differing reasons. In [those cases] the Plaintiff alleges that the mere violation of the standard of care, followed by billing Medicare for the defective procedures, was a violation. Conversely, in this case the Government utilizes the standard of care as a measuring stick to demonstrate that *not all necessary medical acts that were billed for were actually performed*.

NHC, 115 F.Supp 2d at 1155, n. 4 (emphasis added).

Second, the *NHC* court explains, "[t]he billing dispute at issue here is not *how* the Defendant turned, bathed, administered drugs to, and fed the two residents in question, but *whether* the Defendant did these things at all." *Id.* at 1155 (emphasis original).

Clearly, the case at bar falls into the former category in both of these contrasting pairs. As the District Court pointed out, Petitioner in this case does not claim that vascular physicians did not perform any services at all. Instead, he claims that when physicians reviewed the "negative" DVT worksheets they did not perform services "in any reasonable sense or meaning of the word." District Court Opinion, Pet's App. A at 19a-20a (citing Pla's Brief at 9).

F.Supp. 1485 (W.D. Okla. 1996) as examples of the latter type of case.

Thus, Petitioner is correct that *NHC* stands for the proposition that the applicable standard of care can be highly relevant to finding falsity under the FCA. However, the central holding of *NHC* is that if the violation of the standard of care results in no services being provided, a FCA claim may be stated, but not, as in the instant case, where the argument is that the services actually provided were merely inadequate. Ultimately, Petitioner's attack of the District Court's decision regarding the standard of care, including his reliance on *NHC,* is ineffective.

IV There is no question that the District Court employed the correct *scienter* standard under the False Claims Act.

Quite apart from Petitioner's claim that the District Court erred in making findings on scienter, as explained in Section II above, Petitioner argues that the District Court erred by employing an incorrect legal standard for scienter under the FCA. Pet. at 24-27. According to Petitioner, "[w]hereas the statute does not require a specific intent to defraud[,] the trial court did." *Id.* at 25.

Petitioner's argument is at best careless and at worst disingenuous. Petitioner specifically finds fault with the following portion of the District Court opinion:

> . . . to prevail under § 3729(a), a plaintiff must establish at least three elements: first, that the defendant knowingly presented or caused to be presented a claim to the United States for payment or approval; second, that the claim was false or fraudulent, and third, that the defendant knew the claim was false or fraudulent.

Pet. at 25 (citing District Court Opinion and Order of February 18, 2000, Pet's App. A at [9a]) (emphasis added by Petitioner). Petitioner insists, "IT WAS ERROR FOR THE TRIAL COURT TO HOLD THAT THE STANDARD WAS THAT THE 'DEFENDANT KNEW THAT THE CLAIM WAS FALSE.'" Pet. at 25 (emphasis in original). Rather, according to Petitioner, the District Court should have recognized that under the FCA,

> "knowing" and "knowingly" mean that a person, with respect to information–(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

Pet. at 26 (citing *US v. Mackby*, 243 F.3d 1159, 1165 (9th Cir. 2001).

What Petitioner fails to tell this Court is that in the section of the District Court opinion dealing with scienter, the District Court goes on to recite–and apply–exactly the standard cited approvingly by Petitioner above. District Court Opinion, Pet's App. A at 21a ("The Act's scienter requirement is set forth in §3729(b), which requires either 'actual knowledge' that one is submitting a false or fraudulent claim for payment or approval, acts in deliberate ignorance of the truth or falsity of one's false claim, or 'acts in reckless disregard of the truth or falsity of the claim." (citing *Wang v. FMC Corp.*, 975 F.2d 1412, 1420 (9th Cir. 1992)). In fact, the District Court explicitly states, "To succeed under the FCA, a relator need not demonstrate specific intent to defraud

the government." District Court Opinion, Pet's App. A at 21a.

Presumably, Petitioner has overlooked this section of the District Court opinion, or he would have hesitated to make the argument that the District Court used an incorrect scienter standard. Whatever the explanation for Petitioner's argument, the District Court used the proper scienter standard, and there is no error to review.

V The Court of Appeals did not err in its use of the *Hagood* and *Hindo* cases to support its affirmance of the District Court.

As Petitioner correctly explains, the United States Court of Appeals for the Sixth Circuit affirmed the District Court's grant of summary judgment for defendants in this case in a seven-sentence, unpublished *per curiam* opinion. Pet's App. B. That opinion cites two cases in support of affirmance: *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465 (9th Cir. 1996) and *Hindo v. University of Health Sciences*, 65 F.3d 608 (7th Cir. 1995). Petitioner argues that the Sixth Circuit's reliance on each was misplaced. However, because Petitioner merely highlights obvious factual differences between these cases and the instant case, without explaining why these differences call into question those cases' applicability, this argument should be rejected.

Petitioner's sole complaint about the use of *Hagood* is that the case does not involve issues of "standard of care," and that the Sixth Circuit nonetheless cites the case in support of the proposition that "[s]ervices falling below a requisite standard of care, without more, is insufficient to state a claim for government reimbursement of venous ultrasound testing

services." Pet. at 27 (citing Opinion of Court of Appeals, Pet.'s App. B). Petitioner points out that *Hagood* dealt not with health care issues, but with the building of a dam--specifically, with the Sonoma County Water Agency's reliance on a cost allocation report prepared by the Army Corps of Engineers when the Agency provided figures to the government, resulting in the government under-billing the Agency for its water usage.[6]

The Sixth Circuit's reliance on *Hagood* is unsurprising. In that case, the Ninth Circuit concluded that the Agency's reliance on the Corps' cost allocation figures was not "false" within the meaning of the FCA because the allocation figures were a disputed legal question within the Corps. *Hagood*, 81 F.3d at 1477. Similarly, in the instant case, the question whether vascular physicians met the relevant standard of care when reading and interpreting negative DVT studies is, at the most, a matter of legal and medical debate, given the ambiguity of the terms "read" and "interpret" in the Health Care Financing Administration's Provider Handbook and elsewhere. *See* District Court Opinion, Pet's App. A at 20a. The Sixth Circuit thus correctly relies upon *Hagood* because it illustrates that "falsity" must be based on something more than mere definitional disputes. Consequently, submitting claims for reading and interpreting these studies cannot be considered "false" or "fraudulent." Thus, the analogy between *Hagood* and the instant case is apt.

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[6] The *Hagood* court characterizes the case as a "reverse" false claims case insofar as defendant's representations to the government did not result in improper payments to defendant, as in the usual false clams case, but instead in the federal government's underbilling of defendant.

Petitioner's argument with respect to *Hindo* is equally unconvincing. Petitioner distinguishes *Hindo* and the instant case on the sole ground that in *Hindo* there was no question that radiology resident physicians provided the health care services they had contracted to provide, while in the instant case there is a question whether the physician's reading and interpretation of technician's DVT worksheets, and subsequent preparation of a report, constituted "physician services" in any meaningful sense of the word. Pet. at 29.

This distinction is insignificant. It is true that, in *Hindo*, the alleged false claim did not center on the nature of services performed by radiology resident physicians. Rather, that case involved the residents' medical school submitting to the Veterans Administration ("VA") hospital a claim for reimbursement of the salaries of the school's radiology residents who worked at the hospital. The medical school had paid the residents with the understanding that the hospital might obtain funding for the salaries and subsequently reimburse the school. The hospital mistakenly paid the medical school's claim. Plaintiff alleged that the school submitted the claim "falsely"–that is, knowing that the hospital had not received funding, and yet hoping for payment through the hospital's oversight. Plaintiff presented no evidence of fraudulent intent by the school.

The Seventh Circuit decided that the medical school's billing of the VA hospital was not "false" within the meaning of the FCA because the school "could safely assume that if funding had become available, it would be repaid; if the funding had not been approved, it would not be repaid for the residents. . . .[W]hen the University invoiced the radiology residents' costs, the Medical Center was in the best position to ascertain whether funding had been obtained." *Hindo*, 65 F.3d at 614.

Like its reliance on *Hagood*, the Sixth Circuit's reliance on *Hindo* is unremarkable. *Hindo* informs the outcome of the instant case because it involves the question of whether it is knowingly fraudulent to submit claims for which defendants believe, in good faith, payment may be appropriate. Petitioner's objection to the application of *Hindo*, therefore, on the grounds that the cases are factually different, rings hollow.[7]

Petitioner's attempt to manufacture error at the appellate level, like his corresponding effort at the trial court level, is unsuccessful.

CONCLUSION

For the reasons stated above, Respondent respectfully requests that the Petition for a Writ of Certiorari be denied. Petitioner alleges no circuit split or decision in conflict with Supreme Court jurisprudence, and Petitioner's argument for the national importance of this case is extremely weak. Furthermore, the decisions below are based upon clear precedent that even if Respondent had violated applicable regulations or failed to comply with the relevant standard of care–which it did not–these do not alone establish "falsity" under the FCA.

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[7] In fact, it appears that Petitioner would benefit from a more careful reading of *Hindo*. Petitioner implies that it was the VA hospital, and not the medical school, that was accused of violating the FCA. *See* Pet. at 28-9 ("The problem in *Hindo, supra*, rather was that the VAMC [i.e. VA Medical Center] never successfully obtained funding for the services it accepted.") Petitioner's confusion regarding the parties' roles in *Hindo* does not inspire faith in his analysis of the case.

Petitioner's overriding argument throughout these proceedings has been that defendants did not "read" or "interpret" ultrasound studies within any reasonable meaning of those words. However, as this Court will surely recognize, to call defendants' actions "fraud" within the terms of the FCA would be appropriate "[o]nly in Humpty Dumpty's world of word games. . . " *Luckey*, 182 F.3d at 732. "Perhaps [Petitioner] could persuade the [Health Care Financing Administration] to require more or different testing; but when," as in this case, Petitioner "complies with the existing regulations, it is entitled to represent to the government (and the world) that it has done so, without facing a claim of deception." *Id.*

Respectfully Submitted,

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